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CAH Reloc

June 24, 2005

1100 am ✓

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Comments of the
National Council of Health Facilities Finance Authorities

April 25, 2005 Proposed Rule
Changes to CAH Eligibility Rules
**Code CMS - 1500-P**

This Comment is filed on behalf of National Council of Health Facilities and Finance Authorities (NCHFFA). NCHFFA is an association of 28 statewide authorities and the Philadelphia, Pennsylvania authority mandated under state law to provide tax-exempt financing for non-profit, health-care facilities. Since 1990, NCHFFA members have issued over $50 billion of healthcare bonds.

NCHFFA members provide critical access to capital finance for small rural hospitals and other health care entities throughout the United States. Since this mission is to provide access to the lowest-cost financing possible, they are vitally interested in the proposed changes to the requirements for Critical Access Hospitals in the April 25, 2005 proposed rule.

The essence of the proposed CMS regulation is that a CAH designated under the "necessary provider state waiver" can only build a replacement facility if it builds on its campus, as strictly limited, or its plans to rebuild are undertaken prior to December 8, 2003. As a practical matter, this means that many rural health care facilities which are effectively land-locked, restricted by zoning changes or have the opportunity for a better and cheaper location for a new facility -- albeit one serving essentially the same community -- will not be eligible to remain a CAH unless they already have a new facility construction underway. This proposed restriction undermines congressional support for rural hospitals and makes it extremely difficult for authorities to carry out their statutory missions of supporting and enhancing the infrastructure and equipment, which allows for high-quality care.

Many relocation projects which were developed in the last year and a half will be in jeopardy if they do not have construction plans under way by December 8, 2003. More broadly, the proposal leaves no future flexibility to relocate facilities as this becomes necessary due to aging. There is nothing about the mission or the essential location of a facility which should be

affected by the arbitrary and random circumstance of whether it is in a position to relocate to the same or contiguous property or may need to do so a few miles away as long as the same program and essentially the same employees are serving the same population. Many of these facilities were built after World War II, are 40-50 years old or older and should not be perpetually prohibited from replacing or relocating their facility. Residential neighborhoods have located around some of these small campuses and it is now inappropriate or impossible to build at the same location.

Instead of applying a firm, draconian December 8, 2003 date, CMS should rely on the other portion of the proposed rule that would require that "the CAH will be servicing the same community and will be operating the same services with essentially the same staff." That substantive requirement is consistent with the grandfather that Congress contemplated. How does CMS protect the federal budget by forcing a facility to retrofit and thereby often incur higher labor costs in operating in such a building, versus the more productive and less expensive economics of rebuilding?

A few examples are illustrative.

**Wisconsin** - Wisconsin has slightly more than 50 rural hospitals with the CAH designation. In the past 10 years the Wisconsin Health and Educational Facilities Authority has financed 10 replacement hospitals located at new sites but serving the same patient service areas. In each case, replacement was determined to be more cost effective than renovation of the current location.

If a CAH loses its designation because it relocated, the Wisconsin authority will have substantial difficulty in securing financing for that hospital's capital projects. Access to capital will be severely restricted and will be of a lesser amount. It is highly likely that it will cost much more for any loan secured without this designation (estimated at least $20,000 per $1 million borrowed per annum). For example, for a $25 million dollar replacement hospital this could total $7.5 million dollars in additional interest expense.

**Idaho** - Idaho has 23 CAH which make up almost 55% of all hospitals in the state. Three of these "necessary providers" would now be ineligible for CAH status. Those hospitals do not meet required fire and life safety codes, are over 50 years old, and contain asbestos. They cannot be cost-effectively remodeled and studies have demonstrated they are critical to provide access to health care. These hospitals would be unable to finance a replacement without the CAH cost-based replacement. They have heavy Medicare utilization with a small patient base and few "private pay," fully-insured customers to obtain additional reserves.

**Michigan** - Of the 124 hospitals in Michigan, 23 are CAH and several more are converting to CAH. Under the proposal 3 hospitals would have to terminate their construction

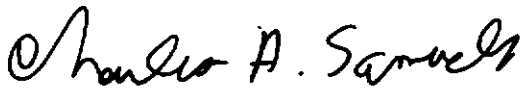
plans. Michigan's CON requirement ensures that hospital relocation is appropriate from cost and quality perspectives.

o o o

We urge CMS to rethink the unnecessary restrictions on relocated hospitals in order to effectuate the purposes of the CAH program and to allow our authorities to continue to assist these critically needed rural institutions.

Respectfully submitted,

MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.



Charles A. Samuels

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June 23, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; *Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates;* Proposed Rule; 70 *Fed. Reg.* 23,305 (May 4, 2005)

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates this opportunity to provide our views on the Centers for Medicare and Medicaid Services' (CMS) proposed rule concerning *Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates* 70 *Fed. Reg.* 23,305 (May 4, 2005).

**DEFINITION OF A HOSPITAL**
**IN CONNECTION WITH SPECIALTY HOSPITALS**

CMS discusses in the proposed rule that "specialty hospitals," as defined under section 507 of Pub. L. 108-173 (MMA), must meet the definition of a "hospital" for purposes of participating in the Medicare program. The proposed rule further states that "[i]n order to be a Medicare-participating hospital, an institution must, among other things, be primarily engaged in furnishing services to inpatients." If CMS determines that an entity is not primarily engaged in inpatient care at the time it seeks certification to participate in the Medicare program, its application for a provider agreement as a hospital would be denied and the hospital would not be eligible for the whole hospital exception to the prohibition on physician self-referrals. In addition, if CMS determines that a specialty hospital that is operating under an existing Medicare provider agreement but is not, or is no longer, primarily engaged in treating inpatients, the hospital would be subject to having its provider agreement terminated and could no longer take advantage of and would lose protection of the whole hospital exception.

The AMA is extremely concerned about several aspects of CMS' discussion regarding whether an entity meets the definition of a hospital. First, CMS states in the proposed rule that to be considered a hospital for purposes of participating in Medicare, an entity must "be primarily engaged in furnishing services to inpatients." This standard is very vague and needs clarity. CMS does not indicate any test that would determine whether a hospital is "primarily engaged in furnishing services to inpatients." The Medicare law also does not define what constitutes "primarily engaged in furnishing services to inpatients."

To further complicate matters, this standard is open to many interpretations. For example, "primarily engaged in furnishing services to inpatients" could turn on the ratio of inpatients to outpatients treated. Yet, with regard to aggregate numbers of services furnished in hospitals, we understand that outpatient services far outnumber the inpatient services provided. Alternatively, this standard could turn on the total revenue a hospital receives with regard to inpatient versus outpatient services. Yet, this likely would discriminate against many smaller hospitals, especially those in rural areas, that do not have as much dollar volume from inpatient services as large, urban hospitals. Other tests for meeting this standard seem equally insufficient. Average daily census or number of beds could constitute the standard, but this could also disadvantage small and rural hospitals since these hospitals may have more difficulty meeting this type of standard.

The "primarily engaged in furnishing services to inpatients" standard was established long ago with regard to traditional hospitals that for the most part furnished "inpatient" services. It may not suffice, however, with regard to today's modern hospitals that modern medicine allows to provide many services on an outpatient basis. According to the American Hospital Association, smaller hospitals with 6-24 beds reported 161,716 inpatient admissions in 2002, compared with 5,929,797 outpatient visits. In the next category, 25-49 beds, 1,062,147 inpatient admissions were counted in 2002. These facilities reported 29,726,357 outpatient visits. This data clearly shows that many hospitals would not meet the "primarily engaged in furnishing services to inpatients" standard. Does CMS plan to terminate each of these hospitals' Medicare provider agreement, or, does CMS plan only to review whether specialty hospitals meet this standard?

CMS states in the proposed rule that if the agency "determines that a specialty hospital that is operating under an existing Medicare provider agreement but is not or is no longer, primarily engaged in treating inpatients, the hospital would be subject to having its provider agreement terminated . . ." (Emphasis added.) Is this an indication that CMS will only review whether specialty hospitals are "primarily engaged in treating inpatients," or, does CMS intend to ensure that all other types of hospitals meet this standard as well?

The AMA adamantly objects to any consideration of applying this standard only to specialty hospitals. The law currently sets forth this same standard generally for all hospitals (except psychiatric facilities) and does not support different standards for different types of hospitals. There is no rational basis to begin arbitrarily applying and/or

enforcing the standard only with respect to specialty hospitals. **It is unclear from the discussion in the rule whether CMS is proposing a separate standard of Medicare participation for specialty hospitals.** We also believe a statutory change would be required to apply a different for traditional versus specialty hospitals.

Any focus by CMS only on whether specialty hospitals meet the "primarily engaged in" standard would be inequitable. CMS has presented no evidence that specialty hospitals do not meet this standard. In addition, as discussed above, this 40 year-old standard is outdated and likely could not be met by many existing general hospitals. Application of this standard only to specialty hospitals would discriminate against specialty hospitals. This would not be in compliance with the law since the standard is meant to be applied across-the-board to all hospitals and since CMS has been applying this standard to all hospitals since its enactment. It would also signal a move to bring patients back into the traditional acute care hospital inpatient setting, which would ignore the fact that because of modern technology, many patients no longer need to spend multiple days in the hospital for procedures that at one time would have required such stays. A recent Department of Health and Human Services report on specialty hospitals, *Study of Physician-Owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003),* shows that these advances not only benefit patients, but are preferred by patients. The report concluded that "specialty hospitals provide a high level of quality of care." HHS found that "structural measures of quality, such as staff specialization and clinical staff per patient, suggest a high quality of care in this dimension. In addition, process of care measures, such as complication rates, also suggest good performance on the part of specialty hospitals." The report also found that "patients responded very favorably to specialty hospitals. Patients who have received care in specialty hospitals value very highly the amenities and services provided . . . . patients responded positively to private rooms, a quiet environment, accommodations for family members, accessibility and attentiveness of nursing staff, specialized training of nursing staff, and the specialized procedures and treatments offered. Patients who received care in specialty hospitals also give high marks to the nursing staff, primarily because of their increased accessibility to patients and their specialization on particular conditions."

CMS has alleged that specialty hospitals do not meet the Medicare definition of hospital and are treating patients in the same manner as ambulatory surgery centers (ASCs), and thus should not be certified as a participating hospital. We do not agree that this is the case. Current Medicare regulations require that ASCs limit surgical procedures to those that, among other things, do not generally exceed: (i) a total of 90 minutes operating time and (ii) require a total of 4 hours recovery or convalescent time. Most specialty hospitals are performing complicated, extensive procedures that require the resources of a full service hospital. Although specialty hospitals furnish "inpatient" as well as "outpatient" procedures, as do most hospitals across the United States, CMS has not presented evidence that the majority of the outpatient procedures furnished by specialty hospitals are those that can be furnished by ASCs, *i.e.*, procedures that may be performed in 90 minutes or less and require 4 hours or less of recovery time. Moreover, it is likely that the number of

outpatient procedures performed in specialty hospitals is generally on par with the average number of outpatient procedures furnished in similarly situated hospitals across the United States.

**In accordance with the foregoing concerns, the AMA does not believe CMS can move forward in determining whether a hospital is "primarily engaged in furnishing services to inpatients," and the vagueness of this standard would seem to preclude CMS from enforcing it. Thus, CMS should withdraw this proposal.**

**MEDPAC RECOMMENDATIONS**

In the proposed rule, CMS also discusses recommendations by the Medicare Payment Advisory Commission (MedPAC) to improve payment accuracy in the hospital prospective payment system (PPS). The AMA agrees with MedPAC that the hospital inpatient PPS needs revision to improve payment accuracy. In fact, the AMA's House of Delegates adopted policy last year that directs the AMA to "support changes in the inpatient and outpatient Medicare prospective payment systems to eliminate the need for cross-subsidization by more accurately reflecting the relative costs of hospital care."

**We are pleased that CMS is moving forward to achieve more accurate payments for hospital services and we support CMS in this effort.**

We appreciate the opportunity to provide our views on specialty hospitals and look forward to working further with CMS to resolve these critical matters.

Sincerely,

Michael D. Maves, MD, MBA

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**Dartmouth-Hitchcock Medical Center**
**Mary Hitchcock Memorial Hospital**

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June 22, 2005

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Wage Data

The purpose of this letter is to comment on the Medicare proposed rule concerning the Hospital Inpatient Prospective Payment System as published by CMS in the Federal Register of Wednesday, May 4, 2005.

By way of background, the Dartmouth-Hitchcock Medical Center (DHMC) is comprised of Mary Hitchcock Memorial Hospital, a 300 bed teaching hospital, the Dartmouth-Hitchcock Clinic, a large academic group practice, Dartmouth Medical School, and the Veterans Administration Hospital. Mary Hitchcock is the only academic tertiary care hospital in the state of New Hampshire, and is one of only a few major rural teaching hospitals in the country.

We are writing to remind CMS that the wage data for Critical Access Hospitals (CAHs) should be removed from the New Hampshire area wage index. We are concerned that the Inpatient Proposed Rule has inadvertently included the wage data for Androscoggin Valley (AVH) (30-0022) in Table 2 of the proposed rule as well as the June 1st corrected tables. The provider's wage data also appears to be included in the calculation of the New Hampshire rural wage index.

The error was originally discovered with the release of the February Public Use File (PUF). We brought this issue to the attention of our fiscal intermediary, after which they spoke with an official at CMS. Our fiscal intermediary has communicated to us that CMS has acknowledged the problem and that an adjustment would be made to remove AVH's wage data from the calculation of the New Hampshire rural wage index. Our fiscal intermediary has assured us that the correction would be made no later than the release of the Fiscal Year 2006 Inpatient Final Rule.

We are still somewhat concerned though, as there appears to be a discrepancy between the May 6th PUF file and the June 1st corrected tables. The wage data for AVH has been removed from the May 6th PUF, but as we previously stated it appears that the AVH

wage data has been included in the June 1st corrected files (proposed rule). Though the discrepancy may be due to timing, we thought that it was important to identify the issue to CMS.

Thank you for consideration of these comments.

Sincerely,

John G. Kelleher

John G. Kelleher
Director, Shared Services

JGK/kjn

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LK MEDICAL CENTER
Lower Keys

Q Data
IMPACT

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June 16, 2005

Centers for Medicare and Medicaid
Department of Health and Human Services
Attn: CMS-1500-P
P.O Box 8011
Baltimore, MD 21244-1850

**Re: Hospital Quality Data" file code CMS-1500-P, as recommended by the Proposed Rule in the May 4, 2005 Federal Register**

Dear Sir or Madam:

Lower Keys Medical Center is a Sole Community Provider in Key West, Florida. We service an isolated population in a rural island chain and provide care that has awarded us a 94% on our 2003 JCAHO survey, and Quality Service scores of 98% and above. We have significant concerns about the use of the QNet 3rd quarter 2004 Validation Assessment score in determining our FY2006 Medicare rates (full market basket update).

The QNet process is relatively new and requires significant human resources. Rural areas characteristically are underserved; sufficient qualified, experienced personnel to respond to all of the demands of CMS, state agencies and the QIO are difficult to obtain. In this situation, due to a misaddressed request for 3rd quarter 2004 Validation data, we stand to be punished with reduced Medicare payments despite the continuance of high quality care to the residents of this island community.

Despite notifying our QIO of the appropriate addressee for correspondence related to this initiative, their requests continued to go to a different department, and therefore the appropriate attention to the Validation request could not be given. We have explained this to our QIO and asked for the opportunity to send in the requested records late. We formally appealed the 3rd quarter Validation Results and sent the records at that time.

They asked that our next quarter's reports (4th quarter 2004) be sent in as much "before" the deadline as possible. We have complied and submitted the 4th quarter's information nearly 1 month ahead of deadline.

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Nearly 16% of the services we provide are to a non-paying, indigent population. Medicare represents 38% of our business and a decrease in our rate would create a considerable impact on our ability to provide a quality, progressive health option to a community that, based upon its location, has few to no other options for acute care.

It seems unjust that for the delinquency of 5 charts, a hospital that served 6,554 patient days to 1,200 Medicare patients in 2004 would have to see a decrease of any kind in its reimbursement. We incurred $17,000 in expenses in 2004 to have an outside audit agency review 100% of the inpatient charts that were sent to Medicare for reimbursement. This agency ensured that there were no coding errors on our submission. Our charges are also run through a third party editor to ensure that charges not allowed by Medicare are not included in our bills. We provided nearly $13 Million in care to the indigent in this community. We maintain a licensed Laboratory and Psych department, along with our participation in the JCAHO program. The delinquency of 5 charts is in no way an indicator of the level of service provided to patients in this community.

The long term impact to facilities, particularly Sole Community Providers, can be devastating. To base such a severe ramification on the review of 5 charts seems unfair. The CMS proposal places a tremendous burden on Sole Community Providers and we request that CMS delay until FY 2007, implementation of their proposal tying the market basket update to the validation assessment to allow rural hospitals adequate notice.

Thank you in advance for your consideration of our comments in making decisions relative to the CMS proposed rules.

Sincerely,

Nicki L. Will, PhD
Chief Executive Officer

MHA
MISSOURI HOSPITAL ASSOCIATION
Marc D. Smith, Ph.D., President

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June 22, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1500-P — Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; FR Vol. 70, No. 85, Wednesday, May 4, 2005, Proposed Rule

Dear Dr. McClellan:

On behalf of the Missouri Hospital Association's member hospitals, health care systems and other health care organizations and individual members, we appreciate the opportunity to submit comments on the fiscal year 2006 inpatient prospective payment system (PPS) proposed rule.

Although MHA supports many of the provisions in the proposed rule, we particularly are concerned about the potential underestimation of the marketbasket, proposed expansion to the post-acute-care transfer policy and proposed restrictions on relocating critical access hospitals with necessary provider status.

## MARKETBASKET UPDATE

Current law sets the FY 2006 inpatient PPS update for hospitals at the rate of increase in the marketbasket, now estimated at 3.2 percent. Legislative and proposed regulatory changes, coupled with technical adjustments to ensure budget neutrality, would result in a proposed average per case payment increase of only 2.5 percent. At the same time, the current estimates of the actual marketbasket increase for FY 2005 is 4.1 percent. We are concerned that CMS is underestimating the marketbasket for FY 2006 dramatically.

The annual update is based on a marketbasket factor intended to reflect the average change in the price of goods and services hospitals purchase for inpatient care. Price changes must be projected forward to estimate increases for the subsequent year so that an appropriate inflationary update can be determined in advance of payment. The Medicare payment system is prospective, and the marketbasket update is not reconciled retroactively to reflect actual price increases for the year. Therefore, a reliable projection methodology is necessary to ensure equitable payments.

For seven of the last eight years, the marketbasket projection has been lower than the actual increase. Although the marketbasket was overestimated for several years before that time, a methodology change was implemented in 1998 that appears to have overcorrected for previous underestimations. For example, the actual increase in FY 2003 was 3.9 percent while the projected increase was 3.5 percent. In FY 2004, the actual increase was 3.8 percent compared to a 3.4 percent projection. Based on the most recent data, CMS reports the FY 2005 marketbasket increase now is estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. MHA is concerned that the methods used to project the marketbasket increase are flawed and fail to provide a reliable estimate of hospital cost increases. Given a 4.1 percent cost increase for FY 2005, a projected FY 2006 increase of 3.2 percent does not seem reasonable. **We request CMS to review and revise the methodology that was used to determine the projected FY 2005 marketbasket update and revise it for the FY 2006 projection, making details of the calculation available to the public.**

## POST-ACUTE-CARE TRANSFERS

Medicare patients in certain diagnosis related groups (DRG) who are discharged to a post-acute-care setting — such as rehabilitation hospitals and units, long-term care hospitals or skilled nursing facilities — or are discharged within three days to home health services are considered a transfer case if their acute-care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount, of as much as the full inpatient PPS rate.

MHA is very disappointed with CMS' continued effort to expand the post-acute-care transfer policy. In the proposed rule, CMS discusses the possibility of expanding the policy from 30 DRGs to either 223 DRGs (later revised to 231) or all DRGs. Specifically, CMS proposes to expand the application of the post-acute-care transfer policy to any DRG that meets the following criteria.

- At least 2,000 discharges to post-acute-care settings
- At least 20 percent of discharges are to post-acute-care settings
- At least 10 percent of discharges to post-acute care occur before the geometric mean length of stay for the DRG
- The DRG has a geometric mean length of stay of at least three days.
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

MHA is frustrated with CMS' continued attempts to find the right criteria to achieve desired budget results, rather than the right policy, regardless of budget implications. This misguided approach of expanding the policy to 231 DRGs will devastate hospitals financially when considering the effects on disproportionate share hospital (DSH), indirect medical education (IME), capital and outlier payments. This is particularly problematic when 75 percent of Missouri hospitals already loose

money treating Medicare inpatients and the aggregate Missouri Medicare margin has dropped every year since 1997 to a current 6 percent loss.

The statute requires CMS to focus on those DRGs with a high volume of discharges to post-acute-care settings and a disproportionate use of post-discharge services. We believe it is inherently impossible for all DRGs, or even 231, to have **disproportionate** usage of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to post-acute-care settings in FY 2004. Clearly, 88 percent of DRGs with any post-acute-care use cannot have disproportionate use. CMS' proposed criteria cast a net far too wide and capture far more DRGs than appropriate.

**MHA objects to expanding the post-acute-care transfer policy because it is not in the best interest of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision making as it penalizes hospitals for providing efficient care at the most appropriate time and in the most appropriate setting. MHA strongly urges CMS to rescind this proposal.**

## OUTLIER PAYMENTS

The rule proposes to establish a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including IME, DSH and new technology payments, plus $26,675. Although this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, we are concerned the threshold is too high. In the proposed rule, CMS states the actual outlier payments for 2005 are estimated to be 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. In addition, the payments in 2004 were 1.6 percentage points lower than the funds withheld.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2003, in combination with the first quarter of 2004, to the last quarter of 2004, in combination with the first quarter of 2005, to establish an average rate of increase. This results in an 8.65 percent rate of change during one year, or 18.04 percent during two years. **The proposed methodology using charge inflation will result in an inappropriately high threshold and a real payment cut to hospitals.** Although MHA appreciates CMS proposing this methodology to avoid using data before the major changes in the outlier policy, **it is unlikely this methodology will result in fully spending the 5.1 percent. MHA strongly opposes using this methodology to estimate the outlier threshold.**

## WAGE INDEX

### Wage Index Calculation Change

The inpatient PPS proposed rule for 2006 contained a change in the wage index calculation. This change was made in step 4 of the "Computation of the Proposed FY 2006 Unadjusted Wage Index" on page 23373 in the *Federal Register*.

The change is in the calculation for "Overhead Wage-Related Cost Allocation to Excluded Areas." This calculation includes the following three steps.

1. Determine the ratio of overhead hours to revised hours.

2. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step 1 by wage-related costs.

3. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in step 1. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step 1, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

**MHA is concerned that CMS would change the calculation of the wage index without discussing the change. We believe CMS should return to the established methodology and proceed with the full notice and comment process before making such a change.**

### Commuting Data

CMS should release and make available the hospital commuting data collected by the Bureau of Labor Statistics used in the out-commuting adjustment. Although, the data are supposed to be available on the Bureau of Labor Statistics' Web site, we have been unable to locate it. This information will assist independent verification of the adjustment calculations and aid independent research of labor market areas.

## MEDPAC RECOMMENDATIONS

The MedPAC recommendations discussed in the proposed rule resulted from a concern that limited-service providers were at an unfair advantage under inpatient PPS. However, it is unclear how such changes will affect the remaining PPS hospitals. Although MHA supports refining inpatient PPS, care should be taken in such an endeavor, because the majority of hospitals are loosing money under Medicare inpatient PPS. MHA urges CMS to proceed slowly and deliberately with extensive research as a foundation for any proposed changes.

## CRITICAL ACCESS HOSPITALS

Currently, a governor may certify a hospital as a "necessary provider," which allows that hospital to become a critical access hospital even if it fails to meet the distance requirement of being more than 35 miles, 15 miles in mountainous areas or by secondary roads, away from a PPS hospital or another CAH. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) terminates a state's authority to grant necessary provider status as of January 1, 2006. However, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan before January 1, 2006, to maintain its necessary provider designation.

MHA believes CMS is exceeding its authority and independently developing a policy that conflicts with the law. MMA clearly established Congress' intent to exempt current facilities from the expiration of the necessary provider waiver. Yet, for FY 2006 and beyond, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing site or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- submitted an application to the state agency for relocation before January 1, 2006
- meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area and remains in a health professional shortage area)
- serves the same community (75 percent of the same population, 75 percent of the same services, 75 percent of the same staff)
- complies with the same conditions of participation
- was "under development" as of December 8, 2003, using similar criteria as the specialty hospitals guidelines (architectural plans, financing, zoning, construction bids, etc.)

MHA believes the date restrictions proposed by CMS are unrealistic and unreasonable. December 8, 2003, merely is the date the MMA was signed into law and has no connection to a CAH legal relocation deadline. The ability of governors to newly approve necessary providers expires January 1, 2006, more than two years later than the date enigmatically chosen by CMS for the relocation deadline. Regardless, the law expressly allows those existing providers to maintain their status after that date with no articulated restrictions. **Consequently, CMS must remove the inexplicable date restrictions for relocations that have no basis in law.**

Often CAHs are housed in old buildings that desperately need renovations. However, before conversion, these facilities could not gain access to capital because of their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, because of the stability of Medicare reimbursements covering allowed costs, not because of excessive profits. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology or other essential upgrades. **Such improvements undoubtedly will result in higher quality care, better patient outcomes and more efficient service.**

Many facilities need or choose to rebuild on a new site to be closer to a highway or to connect to municipal water and sewer. Others choose to relocate because of seismic safety concerns or other reasons that will improve patient safety and the quality of care provided. In addition, because many CAHs are landlocked with little or no room for expansion, they have no choice but to relocate if they

must rebuild. **Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.**

CMS has gone too far in trying to paint hospitals that are moving a few miles from their current location as having ceased business and reopened as a **new provider**. This shows a general lack of knowledge about rural areas. These CAHs are integral to their communities and are often one of the largest employers. Moving down the road will not demonstrably change the population served. **We further assert that CMS automatically should consider any CAH that moves within five miles to be rebuilding and not relocating, which makes it the same provider.**

If a CAH moves further than five miles and CMS is concerned about whether the same population is being served, we would recommend an approach similar to the 75 percent test described earlier. However, because these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff and providing 75 percent of the same services are warranted. For instance, natural changes in demographics and the practice of medicine will occur throughout time that may necessitate a change in services when a hospital is rebuilt. Or, a greater reliance on new technology may limit the number or type of staff needed at a newly built facility. **Some flexibility in the measures is needed to allow for such expected changes to meet the community's needs.**

Therefore, MHA recommends CMS alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show that the change in services provided would be appropriate through a needs assessment, then the test of 75 percent of the services should not need to be met. If a CAH has undertaken a cost comparison that shows that a new facility on another site would be less expensive than rebuilding on the current location, then only two other measures should need to be satisfied. **A combination of criteria suggested would offer CAHs some flexibility and allow for the natural development and maturation of the CAH and the community.**

Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when counting the staff, how should the hospital ascertain if the staff would continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? Is the fact that you plan to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. **CAHs need clear expectations and advanced warning of the standards to which they will be held.**

CAHs are the sole providers of inpatient acute-care services in their communities, as well as outpatient and long-term care services. Facilities converting to CAH status do so because of their dire financial conditions under any PPS. Thus, it is unlikely they would be able to successfully convert back to inpatient PPS. In addition to the lower reimbursement, there would be other hurdles — such as obtaining licenses for additional beds in certificate of need states or hiring

additional staff to expand services when there are shortages in many areas — that would need to be surmounted in an effort to build volume to survive under any PPS. For many of these CAHs, loss of their status would force them to close. **Given the role of these facilities in their communities, such closures would have devastating effects on rural health care access.**

**We urge CMS to rescind this overly restrictive policy and allow necessary provider CAHs to relocate as needed to improve the care and meet the needs of their communities. CMS should expand and use the recommended criteria.**

## DSH ADJUSTMENT DATA

Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. MHA believes this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine if the data based on the federal fiscal year or their own fiscal year is advantageous.

**MHA supports CMS' plans to release a MedPAR limited data set for both SSI and Medicare.**

**However, MHA strongly objects to CMS' decision not to make Medicaid information available.** Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA states the Secretary of the U.S. Department of Health and Human Services must arrange to provide the information **hospitals need** to calculate the Medicare DSH payment formula. This same section the MMA version passed by the U.S. House of Representatives specifically states the Secretary is required to provide the information to hospitals so they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital community has brought this issue regarding the problems of obtaining Medicaid information from the state programs to CMS' attention for several years. Efforts were made through the Medicare Technical Advisory Group to find ways to remedy this problem, but CMS continues to ignore this problem.

In the rule, CMS states it believes hospitals are best situated to provide and verify Medicaid eligibility information and that mechanisms currently are in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting and justifying the Medicaid days is problematic in many states. Although some improvements have been made in the process for obtaining Medicaid eligibility and payment information from the states, wide variation still exists in the breadth of information provided, as well as its accessibility and reliability. In addition, the information from the states still must be processed to match claims data with eligibility data and then manipulated to develop reports that are acceptable to the fiscal intermediary. This is a complex process that is time consuming and labor intensive. As a result, hospitals often find it necessary to hire consultants who have the required expertise and computer programs.

Moreover, the penetration of Medicaid managed care can create an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals.

**MHA recommends CMS impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information. MHA also recommends CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state. The state must make this information available to the providers and contractor audit staff.**

## SPECIALTY HOSPITALS

In the inpatient PPS notice, CMS reported some specialty hospitals may not meet the Medicare statutory definition of a hospital and were not eligible for Medicare certification as a hospital or for the protection of the "whole hospital" exception under the federal physician self-referral law. This conclusion appears to be drawn from their review of applications for grandfathering under Sec. 507 of the MMA that imposed an 18-month moratorium on physician self-referrals to new specialty hospitals.

Undoubtedly, it also was drawn from the fact that both MedPAC and CMS congressionally-mandated studies of specialty hospitals had been unable to include surgical and orthopedic hospitals in many of their analyses because they had so few inpatient admissions. It appeared many specialty hospitals, especially surgical and orthopedic hospitals, were focused primarily on outpatient surgery.

Subsequently, in testimony before Congress, CMS announced its plan to revisit the procedures by which applicant hospitals are examined to ensure compliance with relevant federal standards, as well as an examination of how specialty hospitals should be treated under the Emergency Medical Treatment and Labor Act. Further, CMS indicated its fiscal intermediaries had been instructed to refrain from processing further Medicare participation applications from specialty hospitals until a comprehensive review of its enrollment process was completed. This process is expected to take at least six months.

On June 9, the day after the congressional moratorium expired, CMS issued a fact sheet outlining next steps. The fact sheet provided additional details on CMS' plans to solicit input on these issues. It also indicated the instructions to fiscal intermediaries included suspension of authorization for initial surveys by state agencies during the review period. Finally, it indicated that the suspension would not apply to specialty hospitals that had submitted an enrollment application or requested an advisory opinion regarding grandfathering under the moratorium before June 9.

**MHA commends CMS for recognizing this problem, for undertaking this review and for suspending enrollment applications in the interim.**

**CMS should focus on what the public expects of any entity labeled "hospital" whether full-service or limited-service hospitals.** All Medicare-certified hospitals should have to meet all relevant Medicare conditions of participation, but the **core requirements that CMS should stress for specialty hospitals (some existing and some suggested new requirements) are:**

- **Adequately staffed inpatient capacity**
- **Ability to deal with complications that may arise during or after a surgical procedure in a way that protects the patient's well-being; specialty hospitals should disclose to their patients up front that if complications occur outside their limited capability, patients will be transferred to another hospital.**
- **Ability to deal with emergencies**
- **Discharge planning process and relationships with post-acute providers in the community**

CMS should look at a hospital's operation comprehensively to ascertain whether the facility is **seriously** engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care.

CMS should apply the suspension of processing enrollment applications for all specialty hospitals until its review is completed and appropriate revisions adopted.

CMS should use its authority granted under 1861(e)(9) and 1877(d)(3) of the Social Security Act to extend the application of the moratorium's conditions for grandfathering of existing limited-service hospitals owned by physicians until CMS completes its review and Congress acts on pending legislation regarding self-referral to limited-service hospital owned by a physician.

MHA appreciates the opportunity to submit these comments on the proposed rule. If you have questions regarding our comments, please contact me at 573/893-3700, ext. 1347 or *dfine@mail.mhanet.com* or Gary Toliver, MHA vice president of federal relations, at ext. 1336 or *gtoliver@mail.mhanet.com*.

Sincerely,

Dwight L. Fine

Dwight L. Fine
Senior Vice President of Governmental Relations

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# DEPARTMENT OF NEUROLOGY

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Date: June 22, 2005

To; Centers fo Medicare and Medicaid
Dept. of Health and Human Services
Attention: **CMS-1500-P**
PO BOx 8011
Baltimore, MD 21244-1850

To whom it may concern,

I am writing to support a change in the DRG classification for ischemic stroke patients that receive thrombolytic therapy. I am an assistant professor of neurology at the Medical College of Wisconsin and Froedtert Hospital, in Milwaukee. I also serve as the medical director of our Stroke and Neurovascular Program, since it's inception in 1996. Our program has had a 24/7 stroke team in place since 1996, initiated specifically to provide neurological expertise for acute stroke patients who may be candidates for intravenous tPA. We have evaluated hundreds of acute stroke patients in the emergency department, and treated nearly 130 with thrombolytic therapy. Over time, our services have expanded to include intraarterial thrombolytic therapy, neurocritical care, and a multidisciplinary Neurovascular service. We were one of the first hospitals nationwide to receive certification as a primary stroke center from the Joint Commission for the Accreditation of Hospital Organizations.

I have become a strong advocate in our region for acute stroke care, and am frequently consulted to provide education. Besides my clinical stroke practice, I have provided thousands of hours of stroke education to my professional colleagues and community groups regionally. Furthermore, I have served on many committees and boards in our state to promote stroke awareness and education, including the American Heart and Stroke Association (AHA) on a task force dedicated to promoting stroke awareness among health care providers in our area, the AHA Board of Directors, and the Wisconsin Stroke Committee sponsored by our state Department of Public Health in union with the AHA, with the goals of facilitating that all hospitals in the state become "stroke-ready".

My role as stroke specialist and educator has provided me a unique vantage point regarding the state of affairs with regard to stroke care, in our region. I observe a persistent and pervasive undercurrent against the proactive use of thrombolytic therapy in stroke. Without exception, all area hospital systems I visit use tPA rarely. While limited systematic hospital resources play a role in tPA underutilization, I believe the greater resistance is from treating physicians. The present reimbursement system for physician services provides a dis- incentive to use thrombolytics. I will explain: Most hospitals elect to defer tPA decisions to a neurologist. A stroke call necessitates that a neurologist urgently leave a busy practice to evaluate an acute stroke patient. If tPA is given, that doctor may attend at the bedside from 1 to 3 hours. With the current reimbursement system, the 99.10 thrombolysis code is not reimbursed. So instead, physicians usually bill a level 5 consult. In comparison, a 20 minute new patient consult in the office can be billed the same as the labor and time intensive stroke patient. (The option of billing critical care time is available, but requires "creative" billing that most physicians feel uncomfortable doing.) **This reality- that tPA is underused because of poor reimbursement for the *physician*- is NEVER spoken aloud.** What liability conscious physician would ever admit they avoided giving tPA because it isn't financially rewarding? Instead, every physician rationalizes why this or that patient "isn't a good candidate," can defer seeing that patient until other priorities (ie. Office visits) clear, and skirts the real issue.

There are no statistics to support this, as it is not reported. The fact that since 1996, tPA use has not risen above 4% of the acute stroke incident cases, supports my observations. Until the significant physician time required to actually use tPA (and the lost revenue from evacuating a busy office practice) is compensated, I do not believe that better education nor hospital reimbursement will matter. Some physician with stroke experience must evaluate the patient, discuss risks and benefits, review the relevant history, lab, and imaging data, and decide to treat. Hospital systems must address this requirement. Perhaps the key may be in better support of hospitals through a new DRG, who in turn support stroke team physicians with a salary or financial incentive. Alternatively, physician reimbursement codes (ICD-9) should be revised to reflect the considerable time and effort dedicated to the acute stroke patient.

As a regular provider of tPA to stroke patients, I can attest to it's remarkable efficacy. Others have shown a significant cost savings to society by proper use of tPA. Nevertheless, individual hospitals and physicians are bearing the front loaded costs of this brain saving therapy. As a result, few patients have access to the treatment, which will not change without considerable re-distribution of the relative costs and savings. For the sake of those patients who can't get to a program like ours, I desperately hope for a real change in the reimbursement system.

We share a common compassion for the Medicare beneficiaries at risk for stroke, and I thank you for your dedication. I am eager to help in any way possible, and welcome further discussion.

Sincerely,

Diane Book

Dr. Diane Book
MedicalCollege of Wisconsin
Dept. Neurology
Director Stroke and Neurovascular Program
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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Boulevard
Baltimore, MD 21244-1850

We appreciate the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment system, published in the May 4, 2005, **Federal Register**. We are a major CPA and consulting firm serving approximately 500 hospitals nationwide.

**Occupational Mix Adjustment**

CMS proposes to continue adjusting 10% of the wage index by an occupational mix adjustment. CMS noted last year some confusion and inconsistency with the data accumulated in the first occupational mix survey. We recognize this survey process was new to providers, intermediaries and CMS, and agree that there is likely a great deal of inconsistency in the way different hospitals completed the survey. For this reason, we encourage CMS to revisit this process immediately, and gather new data within the next year, rather than waiting two more years before obtaining such data. At the same time, more detailed instructions should be issued to clarify the types of data reported, and how occupational data should be recorded on the survey form. CMS notes that a **Federal Register** notice will be published outlining changes to the survey process, and we look forward to reviewing this notice.

**Hospital Redesignations and Reclassifications**

Table 9C lists those hospitals that have been redesignated rural under section 1886(D)(8)(E) of the Act. Provider No. 26-0195 was so redesignated by letter from the Kansas City Regional Office dated December 16, 2004, and should be added to Table 9C.

The narrative on Page 23378 states that Chart 6 from the FY 2005 final rule incorrectly included Monroe, PA and Walworth, WI as counties qualifying for redesignation under Section 1886(d)(8)(B) of the Act. However, the chart on Pages 23379-23381 continues to list those two counties. We request clarification as to whether or not they qualify for redesignation.

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The existing policy for Section 1886(d)(8)(B) (Lugar) reclassification is becoming problematic for an increasing number of hospitals. Congress intended for Lugar reclassification to benefit hospitals located in counties that meet the criteria. However, some hospitals are finding that the Lugar reclassification is actually a disadvantage because it forces the affected hospitals to be treated as urban for all purposes.

In some cases, hospitals located in Lugar counties would prefer to reject the Lugar reclassification and remain as rural. In many cases, a hospital can only qualify for special payment provisions if they are considered rural. This includes critical access hospitals (CAH), sole community hospitals (SCH) that are less than 35 miles from another general acute care hospital, Medicare dependent hospitals (MDH), and rural referral centers (RRC).

While it is true that some of these negatively-affected hospitals may be able to qualify for urban to rural reclassification under 42 CFR 412.103, not all affected hospitals can necessarily meet the criteria. Also, the 412.103 provisions can be somewhat cumbersome and prevent such hospitals from seeking reclassifications through the MGCRB process.

Nothing in the statute appears to specifically prevent CMS from allowing hospitals to reject Lugar. Congress clearly intended the provision to be a benefit and not a detriment to affected hospitals. Accordingly, we believe that it would greatly simplify certain situations if CMS would allow hospitals to reject Lugar reclassifications in the same manner in which it allows for hospitals to have a choice in other reclassifications.

**Out-Migration Adjustment**

Table 4J lists hospitals eligible for a Section 505 out-migration adjustment. A new Table 4J was posted on the CMS website on June 1, 2005. While many of the providers are unchanged on this revised table, several have been removed. An example would be Provider No. 33-0175. The commentary at the top of the revised table does not explain these removals. We would request clarification as to why providers have been removed from the original Table 4J.

**Postacute Care Transfers**

CMS once again proposes to expand the postacute care transfer (PACT) policy. In describing the proposed expansion, CMS notes that, of 507 active DRGs, 220 have lengths of stay of less than 3.0 days and 64 have fewer than 100 short-stay transfer cases. CMS proposes to include the remaining 223 DRGs under the PACT policy. Based on revised data posted to the CMS website, we understand there are now 231 DRGs proposed to be included under the PACT policy. We do

not believe the proposed changes are in compliance with Section 1886(d)(5)(J) of the Act. This section requires that DRGs included under this policy must have "a disproportionate use of post discharge services."

While CMS notes that each of the selected DRGs had at least 2,000 PACT cases, CMS does not explain how this represents a "disproportionate use" of post discharge services. The plain meaning of the word "disproportionate" would indicate that, for a DRG to be included under the PACT policy, the usage of post discharge services would have to be outside the norm. CMS previously published criteria that somewhat accomplished this goal, by requiring 14,000 PACT cases for a DRG to be included under the policy. By excluding the 220 DRGs with lengths of stay of less than 3.0 days, CMS effectively proposes to include every other possible DRG under the policy that had 100 or more transfer cases.

To demonstrate that it has met the intent of the law, CMS should publish a complete list of all DRGs, showing how many total cases each DRG had, and how many of those cases included usage of post discharge services. The usage rate should also be computed for each DRG, as well as the overall average usage rate. We believe a usage rate at least one standard deviation above this average should be set as a minimum before a DRG is made subject to the PACT policy. We do not believe any change is needed in the current PACT policy. However, if CMS does propose such a change, we believe the clear intent of the law is to limit the PACT policy to DRGs with a disproportionate use of post discharge services, something CMS does not demonstrate with its proposal.

Further, we do not believe that CMS is required to implement changes to the PACT policy as actual reductions in Medicare spending. We request CMS make the postacute transfer policy a budget neutral policy, such that any reductions in Medicare spending through revisions to this policy be paid to providers through an increase in the PPS update factor or the budget neutrality adjustment.

**Sole Community Hospitals and Medicare Dependent Hospitals**

CMS proposes to modify the budget neutrality adjustment applied to hospital-specific payment rates for SCHs and MDHs, to no longer consider changes in the wage index when applying the budget neutrality adjustment to hospital-specific payment rates. However, CMS fails to quantify the impact of this proposal. We request more detailed information regarding the impact of this change on fiscal 2006 payments, as well as the impact if this change was imposed retroactively.

**DSH Adjustment Data**

We appreciate the efforts CMS is making to comply with Section 951 of the Medicare Modernization Act, which required that CMS make certain DSH adjustment data available by December 8, 2004. CMS notes that a future **Federal Register** notice will publish more details on this issue. Due to the significance of this issue and the time that has already elapsed since December 8, 2004, we request that CMS expedite its efforts to make such data available.

**Geographic Reclassifications**

CMS proposes to update 42 CFR 412.103(a)(1) to use Rural-Urban Commuting Area codes to identify hospitals located in rural census tracts. However, it was difficult to locate these codes by going to the website identified in the proposed regulations. We request further clarification concerning these codes, or a more detailed website reference as a link to the codes.

**Critical Access Hospitals**

We are very concerned about the proposed policy change related to replacement or relocation of a critical access hospital (CAH) that has been designated as a necessary provider (NP).

We are opposed to the proposed December 8, 2003, deadlines related to CAH replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. The replacement deadline relates to ownership of contiguous land, while the relocation deadline relates to documenting plans to relocate the CAH. The proposed "75% threshold" is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original necessary provider designation, i.e. that the "CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees). . ." We do not believe either deadline is needed as long as the 75% thresholds are met. This would include adding the 75% thresholds to the requirement for replacement on contiguous land.

Our basis for this position is as follows:

1. It was clearly not the intent of Congress in the Medicare Modernization Act that a CAH designated as a necessary provider be perpetually prohibited from replacing or relocating their facility, facilities that are often 40 to 50 years old. MMA Section 405(h) by its clear wording only precludes the designation of new CAHs under the "Necessary Provider" exception to the

CAH mileage criteria. And the last paragraph of Section 405(h) made very clear Congressional intent to grandfather existing necessary providers as of January 1, 2006. We request CMS cite the statutory authority for the proposed rule that would strip necessary provider status from a CAH that would otherwise qualify for that status, simply because a construction project was not under development by December 8, 2003, or not on land owned prior to that date.

2. Many rural hospitals are aging facilities that may have difficulty maintaining their hospital licenses because of facility problems. If CMS is to implement any such drastic changes that generally prevent hospitals from relocating their facilities, exceptions must be included for hospitals forced to rebuild because of facility licensing issues.

3. Many rural hospitals are located on a small campus in the middle of residential neighborhoods with relocation being the most appropriate, and sometimes the only, alternative. The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild its hospital at a nearby location may cost Medicare more over time, not less. Over time, the higher labor costs of operating in a retrofitted building may more than offset the higher initial cost of rebuilding.

4. A ban on major construction projects developed after December 8, 2003 is an unnecessary added burden on CAHs. CMS' concern about a provider using its CAH designation to fund a new facility serving a different market can be appropriately managed by the portion of CMS's proposed rule that would require assurance that, after the construction, the CAH will be serving the same community and will be operating essentially the same services with essentially the same staff.

We would request one clarification on the 75% tests. The tests related to services and staffing should be relatively easy to document. The test related to serving the same service area is generally measured from historical data. We request clarification that CAH status is grandfathered until one year has elapsed in the new facility, after which the service area test is measured from historical data, perhaps with 180 days after completion of the first full year of operation in the new facility to conduct the test.

A CAH's necessary provider designation is associated with its current Medicare provider agreement that remains intact unless the CAH fundamentally changes its business (e.g., ceases its current operations) or is terminated by Medicare. It is a longstanding policy that the provider agreement describes the legal entity and services provided—not the physical structure or location.

***Conclusion***

Again, we appreciate this opportunity to submit comments. Please contact Tim Wolters at 417-865-8701 if you have questions or need further information concerning our comments.

**BKD, LLP**

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***By Overnight Courier***

Centers for Medicare and Medicaid Services
Attn: CMS 1500-P
Room C5-14-03
Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1500-P
Hospital Inpatient PPS Proposed Rule for FY 2005
Postacute Care Transfers, DSH Adjustment Data, Graduate Medical Education, Provider-Based Entities, Geographic Reclassifications

Dear Sir or Madam:

St. John Health, a Southeast Michigan, not for profit health system that includes eight acute care hospitals with over 400 allopathic and osteopathic residents currently in training welcomes this opportunity to comment on the proposed rule (the "NPRM") promulgated by the Centers for Medicare and Medicaid Services ("CMS") entitled *Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates* (70 Fed. Reg. 23306 (May 4, 2004)). St. John Health hospitals include:

St. John Hospital & Medical Center, Medicare # 23-0165

Providence Hospital & Medical Center, Medicare # 23-0019

St. John Detroit Riverview Hospital, Medicare # 23-0119

St. John Macomb Hospital, Medicare #23-0195

St. John River District Hospital, #23-0241

St. John Northshores, Medicare #23-0257

St. John Oakland Hospital, Medicare # 23-0223

Brighton Hospital, Medicare # 23-0279

**Postacute Care Transfers**

The Hospital strongly disagrees with CMS' proposed changes to the post-acute care transfer payment policy. Under criteria presently in effect, cases assigned to one of 30 designated DRGs are paid as transfers when the patient is discharged to a post-acute care setting. 70 Fed. Reg. at 23413. In the NPRM, CMS has proposed to expand this policy to include all DRGs that have the following characteristics: (a) the DRG has at least 2,000 post-acute care transfer cases; (b) at least 20 percent of all cases in the DRG were discharged to post-acute care settings; and (c) 10 percent of the post-acute care discharges occurred prior to the geometric mean length of stay for the DRG. *Id.* at 23416. As a result of this proposal, 223 DRGs[1] would be subject to the post-acute care transfer payment policy, representing a seven-fold increase over existing policy. *Id.*

The Hospital asserts that CMS' proposal is inconsistent with both the intent of the governing statute, as well as with the strong policy frequently articulated by CMS for both providers and CMS to know prospectively the amounts payable for covered services. The statute specifically mandates that CMS' selection criteria for DRGs which shall be paid as transfers when the patient is discharged to post-acute care must take into account whether cases assigned to the DRG reflected a "disproportionate use of post discharge services." SSA, § 1886(d)(5)(J)(iv) (referring to (J)(iii)(I)). By definition, "disproportionate" must be measured relative to a norm. It is a statistical impossibility for half of the universe of DRGs to have "disproportionate use of post-discharge services."[2] For treatment of a discharge as a transfer, CMS has established the low threshold that 20 percent of the cases in the DRG are discharged to post-acute care. 70 Fed. Reg. at 23416. CMS' proposed rule and the rulemaking record includes no data on how frequently Medicare patients discharged from a hospital need some post-acute care services.

In proposing to include almost half of all DRGs in the post-acute care transfer payment policy (and apparently more than half of all discharges), CMS can hardly claim that it has only selected DRGs which exhibit a "disproportionate use" of discharges to post-acute care. Rather, even DRGs that exhibit fairly ordinary use of post-acute care services after discharge are encompassed by CMS criteria. Indeed, CMS only requires that **two percent** of discharges for a given DRG be discharges to a post-acute care setting occurring prior to the geometric mean length of stay for that DRG (*i.e.*, 10 percent of 20 percent). This low bar to inclusion does not reflect Congress' intent in creating this policy. Again, the rulemaking record is insufficient because there is no empirical basis articulated by CMS for selecting the 2 percent criterion.

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[1] CMS has characterized these 223 DRGs as having "relatively high volume" but does not disclose what percentage of discharges are accounted for by these 223 DRGs.

[2] CMS' proposed "option one" would treat *all* discharges as transfers. That CMS would propose this illustrates that it has read out of the statute the requirement that discharges treated as transfers reflect a "disproportionate use of post-discharge services."

Indeed, the only evidence considered by CMS actually supports that revisions to the post-acute care transfer payment policy are not warranted at this time. CMS' policy has been to include a DRG within the scope of the policy if, among other factors, there had been a recent decline in the DRG's geographic mean length of stay. *Id.* at 23415. Presumably, this criterion reflects that the purpose of the policy is to create a disincentive to prematurely discharging patients. CMS' data, however, indicate that, even among many of the DRGs experiencing an increase in post-acute care utilization, there has been an increase in lengths of stay. *Id.* The data, as presented by CMS, therefore show that a trend towards higher patient acuity has resulted in a greater need for both acute care and post-acute care services. Yet, by CMS' own description, what drove its criteria was determining which criteria would encompass the vast majority of active DRGs with a length of stay over three days. *Id.* at 23415-16. In other words, CMS has not objectively analyzed its data to determine whether an expansion of the number of DRGs subject to its policy is warranted. Instead, CMS determined first that it would expand its policy and then "reverse engineered" its revised post-acute care criteria from its data.

CMS' proposed policy is also antithetical to the prospective nature of the inpatient reimbursement system. Since its inception, the DRG payment system has focused on setting hospital rates prospectively, such that similar diagnoses would be paid similarly irrespective of the actual resources used in treating a particular patient. *See, e.g.*, SSA, § 1886(d)(2). However, by including such a large percentage of DRGs within the ambit of the transfer payment policy, CMS is essentially converting inpatient PPS into a per-diem payment system with a length of stay cap set at the geometric mean length of stay for that DRG. Not only does this remove incentives for hospitals to be efficient in the delivery of care, but also this policy is patently inequitable in that there is no offsetting payment for discharges that exceed the geometric length of stay and do not involve post-acute care, until the outlier threshold is finally reached. Because this policy is not in accord with Congressional intent and is otherwise inequitable, the Hospital requests that CMS not finalize its proposal.

**DSH Adjustment Data**

While the Hospital appreciates that CMS has now proposed to implement the legislative mandate requiring the release of data used by CMS to calculate hospitals' entitlement to disproportionate share hospital ("DSH") payments, the Hospital believes that the proposed implementation requires some modification. CMS' proposal would release to hospitals data from its MedPAR Limited Data Set (LDS). 70 Fed. Reg. at 23435. The Hospital believes that, standing alone, the MedPAR LDS data is insufficient. CMS' data matching of Supplemental Security Income ("SSI") data against its MedPAR data has often been inaccurate. *See, e.g.*, 60 Fed. Reg. 29202, 29224 (June 2, 1995) (acknowledging that CMS cannot explain why its recalculation of SSI days upon a hospital's request invariably results in a lower count). Accordingly, the Hospital requests that CMS release instead the source data for the SSI days that it receives from the Social Security Administration. Just as CMS has acknowledged that it is allowed to distribute MedPAR LDS data under the routine use exception, CMS' distribution of the source information could be similarly protected. 70 Fed. Reg. at 23435. Congress' mandate requires that CMS furnish data that would allow a hospital to "compute the number of patient days" used in the DSH calculation.

Medicare Prescription Drug, Improvement and Modernization Act (the "MMA"), § 951. Without the source SSI data, a hospital could not truly "compute" its SSI days. The MedPAR LDS data simply shows the results of CMS' computations and therefore does not fulfill the statutory requirements.

Further, the Hospital requests that CMS revise its policies to facilitate greater access to Medicaid data. Although many States may be voluntarily releasing to hospitals the requisite Medicaid eligibility data, State policies are subject to change. Only through an amendment to State plan requirements can CMS ensure that it has affirmatively "arranged to furnish" Medicaid eligibility data, as required by the MMA. MMA, § 951.

**Graduate Medical Education**

The Hospital considers CMS' changes to its graduate medical education ("GME") policies to be salutary. The Hospital, however, believes that several of these proposals could be further refined. In particular, the Hospital believes that CMS' policies with respect to clinical base year training should provide that the initial residency period should be set in the second year of training for all residents in a specialty program, irrespective of whether they matched to that program while still in medical school. Further, the Hospital believes that urban hospitals that establish new medical residency training programs should be allowed to enter into affiliation agreements without limitation.

A. Clinical Base Year Training

As CMS has recognized, many specialty programs require a year of general clinical training, referred to as a "clinical base year" of training. CMS has previously adopted regulations that would allow hospitals to calculate the initial residency period using the second year of training for residents training in specialty programs requiring a clinical base year, provided that the hospital can demonstrate that the resident simultaneously matched to both the first and second year program. 42 C.F.R. § 413.79(a)(10). CMS is now proposing to expand this regulation to allow hospitals to use the second year of training to calculate the initial residency period even where the resident did not match to a first year program. 70 Fed. Reg. at 23439. Although this proposed revision represents a welcome expansion of CMS' clinical base year policy, it still does not properly reflect Congress' intent in enacting the statutory provisions governing initial residency periods.

Since Congress has envisioned a much broader clinical base year policy, CMS should revise its policy to better align it with the pertinent legislative history. As stated by Congress in connection with the initial residency period provisions:

> The conferees also clarify that under section 1886 (h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

Conference Committee Agreement Accompanying Public Law 108–173, 108 Cong., 2d Sess., 276 (2003). In revising its clinical base year policy, CMS should closely adhere to the legislative history relating to the initial residency period provisions. The legislative history does not distinguish between residents based upon their intentions in pursuing a year of clinical base year training. Rather, the initial residency period for any residency program requiring a prior year of clinical base year training in all cases is determined in the second year of training. The Hospital submits that this interpretation of the statute is entirely consistent with the language of the statute, and CMS should thus defer to this interpretation and structure its policy accordingly.

At a minimum, we believe that CMS should also allow hospitals to use the second year of training in all instances in which the resident had undertaken a year of training in a transitional year program or a preliminary position in an internal medicine program. In the case of either a transitional year program or a preliminary year program, the programs do not lead to certification. Instead, residents must complete their training in some other program. Since these residents could never receive certification from the program in which they received their clinical base year of training, the "particular specialty for which the resident is training" is the specialty program begun in the second year. 42 C.F.R. § 413.79(a)(6). Thus, a policy that takes account of transitional year programs and preliminary year programs would squarely accord with the applicable statute and regulation.

B. Affiliation Agreements

The Hospital also requests that CMS consider broadening its proposed changes to the affiliation agreement requirements. CMS has proposed to allow urban hospitals that establish new medical residency training programs to enter into affiliation agreements, provided that the hospital with the new program experiences an increase in its FTE cap pursuant to the affiliation agreement. 70 Fed. Reg. at 23440. CMS has expressed a concern with allowing affiliation agreements in which new urban teaching hospitals experience a decrease in their FTE caps because CMS maintains that such a relaxation of policy would encourage gaming. *Id.* Specifically, CMS believes that hospitals with established medical residency training programs would establish new programs at hospitals that do not yet have any programs and then seek to shift the positions created by this new program to the established teaching hospital. *Id.* The Hospital believes, however, that CMS' concern is unwarranted, and therefore, its policy is too restrictive.

In claiming that affiliation agreement restrictions are necessary for new urban teaching hospitals to prevent gaming, CMS has not properly considered the various safeguards already in place. For instance, any hospital that chooses to establish a new medical residency training program must undergo accreditation by an appropriate accrediting body. 42 C.F.R. § 413.79(*l*). Such action can be an intensive process, involving significant attention by a number of parties across hospital medical and administrative departments. Furthermore, a hospital must maintain its new program for a period of three years before it qualifies to receive a permanent FTE cap. 42 C.F.R. § 413.79(e)(1)(i). In other words, establishing a program requires concerted action by staff throughout a facility, which actions must be sustained for a substantial period of time. It is unlikely that many institutions would undertake such action merely to help another hospital to obtain a purported improper gain in its GME payments.

CMS can also find further protection against potentially inappropriate use of affiliation agreements through changes it has made over time to the affiliation agreement requirements. For example, CMS now requires that there be a bona fide shared rotational arrangement between two hospitals as a pre-condition to entry into an affiliation agreement. 42 C.F.R. § 413.79(f)(2); 42 C.F.R. § 413.75(b). Thus, an established teaching facility could not simply shift to itself an entire program from a new teaching facility because it would no longer be possible to meet the shared rotation requirement. Moreover, an established teaching hospital could never permanently acquire a new program initiated by a new teaching hospital because the new teaching hospital would always have the right to terminate the agreement, which would result in the return of both parties to their initial FTE caps. 42 C.F.R. § 413.79(f)(5). Since an established teaching facility could never be certain of the long-standing intentions of the prospective new teaching facility, it would be discouraged from aiding the new teaching facility in establishing a program simply to circumvent FTE cap rules. Due to these changes in CMS' affiliation agreement policy, restrictions on affiliation agreements for new teaching hospitals are no longer necessary.

As presently proposed, CMS' affiliation agreement policy could have an adverse impact on medical education. CMS has acknowledged that over the course of a year, often there are unanticipated changes in planned rotations. Accordingly, CMS allows parties to file amendments to their affiliation agreements prior to the end of an academic year. 67 Fed. Reg. 49982, 50071 (Aug. 1. 2002). Similarly, a new urban teaching hospital may intend to be a net recipient of residents, but during the year unforeseen circumstances may cause it to shift a portion of residents to another party in its affiliated group. Though these circumstances may be beyond the hospitals' control, CMS would penalize the receiving hospital by not allowing it to increase its FTE cap through a shift of a portion of the new teaching hospital's FTE cap. This lack of flexibility will inevitably discourage parties from entering into affiliation agreements with new teaching hospitals because of the fear of adverse financial implications arising from unforeseen circumstances. Accordingly, since this policy creates a disincentive for beneficial medical education arrangements without any significant offsetting value as a safeguard, the Hospital requests that CMS reconsider requiring new teaching hospitals to enter affiliation agreements only when they result in an increase in their FTE cap.

C. CMS Recognition of Affiliated Groups

St. John Health requests clarification of CMS's stance to recognize affiliation agreements among hospitals who are part of more than one affiliation agreement where one of the agreements specifically exclude affiliation participation with hospitals included in the second agreement. The following example describes the situation.

Hospital A, Hospital B, Hospital C, and Hospital D agree to affiliate for Medicare payment purposes. Hospital D and Hospital E sign a separate affiliation agreement for Medicare payment purposes. The Hospital D and Hospital E affiliation agreement specifically states the agreement's intent is not to include Hospital E as part of the agreement between Hospitals A, B, C, and D.

Does to the agreement between Hospital D and Hospital E specifically excluding Hospitals A, B, C, and D in the affiliation agreement between Hospital D and Hospital E still allow the agreement between Hospital D and Hospital E to meet the requirements of an affiliation agreement for Medicare payment purposes? It is SJH's opinion that the affiliation agreement between Hospital D and Hospital E does not meet the Medicare requirements for affiliation due to Hospital D and E's exclusion of specific affiliation groups that include Hospital D.

However, if the opinion of CMS is contrary, and the affiliation agreement between Hospital D and Hospital E, how will the Hospital D and Hospital E agreement impact the Hospital A, B, C, and D affiliation agreement for Medicare payment purposes?

If the affiliation agreement between Hospital D and Hospital E meets the requirements of an affiliated group, SJH would contend Hospital D should then be excluded from the affiliation agreement with Hospitals A, B, C, however, Hospital's A, B, and C should still be allowed to continue their affiliation agreement.

**Provider-Based Entities**

We support CMS' proposed revision to the obligation in Regulation 413.65(g)(7) for a hospital outpatient department that is not on the main provider's campus to give a notice of coinsurance when no physician service is being furnished in conjunction with a hospital's service. We believe, however, that the proposed exception should be both expanded and clarified as explained below.

The current regulation does not require that a notice of coinsurance be given for services furnished on a main provider's campus. The reason that no notice of coinsurance is required for services furnished on a main provider's campus is because the patient knows that he or she is in a hospital, and that in hospital settings, there are separate charges for the technical services furnished by the hospital and the professional services furnished by physicians. Patients also understand that there will be separate coinsurance amounts for those bills.

The rationale underlying an exception for the notice of coinsurance requirement for a main provider's campus is equally applicable for any hospital campus, whether that hospital is freestanding or is included on another hospital's provider number.

When CMS promulgated the provider-based regulation in 2000, it made clear that the provider-based rule would govern whether two or more hospital campuses could be included on a single provider number. In addition, CMS insisted that only a single campus be the "main provider." Thus, full-service hospitals that are obviously hospitals to anyone entering them can be subject to the notice of coinsurance requirement for any Medicare patient receiving outpatient services, based solely on the fact that they are deemed to be provider-based with another hospital that is the "main provider." There is no rational basis to require notices of coinsurance in outpatient departments of these "provider-based" entire hospitals since they are obviously hospitals and beneficiaries will be aware of the likelihood of receiving two bills with two coinsurance amounts to the same extent as on the main provider's campus or any other hospital's campus.

Accordingly, we strongly recommend that CMS amend the regulation so that the notice of coinsurance requirement does not apply to services furnished within the main buildings of a facility with Medicare certified and available hospital inpatient beds. The logic that supports not requiring a notice of coinsurance for outpatient departments on a main provider's campus is equally applicable in this situation.

In addition, we suggest that CMS clarify what is an "outpatient department" within the meaning of (g)(7). Many departments are not devoted to outpatient services at all but rather serve both inpatients and outpatients concurrently. The most dramatic illustration of this is outpatient observation services that are typically furnished in inpatient routine beds. Similarly, many diagnostic services such as imaging are furnished in ancillary departments that serve both inpatients and outpatients. "Outpatient department" is not defined within the provider-based regulation nor elsewhere within the regulations known as the "principles of reimbursement." To clarify what is an "outpatient department" within the meaning of (g)(7), we recommend that CMS define "outpatient department" as used in (g)(7) as meaning a department whose principal function is to serve outpatients.

**Geographic Reclassifications**

The Hospital requests that CMS make several revisions to its geographic reclassification policies. First, the Hospital believes that CMS should, through FY 2007, allow hospitals to continue to have the option to qualify for qualification for reclassification if either the Combined Statistical Area ("CSA") or the Consolidated Metropolitan Statistical Area ("CMSA") eligibility criterion is met. Further, the Hospital believes that CMS should revise its urban county reclassification provisions to allow hospitals reclassified under Section 508 of the MMA to request a postponement of the reclassification effective date until the expiration of the Section 508 reclassification. Finally, while Section 508 reclassifications remain in effect, the Hospital maintains that urban hospitals should not be required to include hospitals reclassified under Section 508 in any request for an urban group hospital reclassification.

C. Labor Market Area Criterion in Urban Group Hospital Reclassifications

The Hospital believes that CMS should delay implementation of its proposed revision to the qualifying criteria used to determine whether the hospitals within an urban county can reclassify to another urban area. CMS has acknowledged that the FY 2005 changes to labor market areas have been of a significant magnitude. 70 Fed. Reg. at 23437. Accordingly, CMS has allowed for a three year transition period to phase in the payment reductions resulting from the redefined labor market areas. 69 Fed. Reg. 48916, 49032 (Aug. 11, 2004). Notwithstanding CMS' recognition of the sea change represented by the new labor market areas, CMS is now proposing not to allow an urban county group reclassification located in the same CMSA as the urban area to which the group seeks reclassification, unless the targeted urban area is also in the same CSA. 70 Fed. Reg. at 23437. In keeping with the graduated approach towards implementing the new labor market areas, the Hospital requests that CMS delay implementation of this policy until at least FY 2008, which would coincide with the expiration of the payment reduction transition period.

D. Delayed Effective Date for Urban Group Hospital Reclassifications

The Hospital also requests that CMS effect a limited modification to its urban group hospital reclassification rules to account for the timing of the expiration of the reclassifications effected pursuant to Section 508 of the MMA. In accordance with the MMA, hospitals qualifying for reclassifications under Section 508 are allowed to maintain their reclassified status until March 31, 2007. MMA, § 508(a)(3). However, urban group hospital reclassifications take effect as of October 1 of a given year. 42 C.F.R. § 412.274(b). Thus, in FY 2007, hospitals will be faced with the difficult choice of either: (a) sacrificing six months of the Section 508 reclassification so that they can reclassify as part of an urban group in that year (*i.e.*, the period from October 1, 2006 through March 31, 2007); or (b) pursuing no reclassification for a six month span, even though the hospitals otherwise qualify to reclassify as an urban group (*i.e.*, the period from April 1, 2007 through September 30, 2007). In enacting Section 508 of the MMA, Congress intended to create reclassification options for hospitals with limited choices. There is no evidence that Congress intended to force hospitals to forego other reclassification options that would otherwise be available upon the expiration of their Section 508 reclassification. Accordingly, CMS should allow hospitals with Section 508 status to obtain reclassification with a delayed effective date.

E. Partial Urban Group Hospital Reclassifications

Similarly, CMS should not require an entire urban group to simultaneously seek reclassification when some of the constituent hospitals are presently reclassified under Section 508 of the MMA. Currently, CMS regulations require that "all urban hospitals in an urban county must apply for redesignation as a group." 42 C.F.R. § 412.234(a)(1) (emphasis added). When CMS initially promulgated this regulation over a decade ago, it could not have contemplated that Congress would enact Section 508 of the MMA, which has allowed some, but not all, of the similarly situated hospitals within some counties to obtain reclassification. In effect, CMS' regulation twice penalizes the hospitals in these counties not qualifying for reclassification under Section 508: once when they failed to qualify for a Section 508 reclassification, and again when they are unable to obtain unanimous consent to seek reclassification as an urban group. Such a result is inequitable and warrants a limited exception during the period in which Section 508 reclassifications remain in effect.

* * *

Thank you for your review of this submission. Please call me at (586) 753-0099 with any questions regarding these comments you may have.

Sincerely,

David R Buckley

David R. Buckley
Corporate Director of Reimbursement
St. John Health

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June 21, 2005

CVRx®

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir or Madam,

I am the President of CVRx Inc., an emerging medical device company that has developed an implantable device called the Rheos™ Baroreflex Hypertension Therapy™ System. The Rheos device is designed to treat patients with high blood pressure that cannot be controlled with drug therapy. As you know uncontrolled hypertension is associated with a significant increase in stroke, heart and kidney disease and other illnesses. The Rheos system was designed to reduce high blood pressure by using an implantable device-based electrical activation of the carotid sinus baroreflex. The system is currently being evaluated in clinical trials. We have recently been granted IDE approval by the FDA and were given a Category B designation.

CMS has determined that ICD-9-CM code 86.96, "Insertion or replacement of other neurostimulator pulse generator," plus 04.92, "Implantation or replacement of peripheral neurostimulator leads," are the appropriate codes for this procedure. The ICD-9-CM code 86.96 is assigned to DRG 7 or 8, which are "Peripheral and cranial nerve and other nervous system procedures with or without complications." National average payment for DRGs 7 and 8 for 2005 are $12,102 and $7,100 respectively. Unfortunately this payment rate will not cover the cost of the Rheos procedure or the device system.

Figure I below describes the national charges associated with DRG 8. For comparison, the charges for DRG 108, "Other cardiothoracic procedures," are also included. The charges for DRG 108 are included because CVRx believes that the charges for the Rheos system implant will be similar to those for this DRG. The cost for the Rheos system is $20,000, which includes the Rheos Implantable Pulse Generator, two Rheos Carotid Sinus Leads, a Rheos Patient Wand and the use of a customized Computer Programmer. Hospital charges for the implant using a 35% cost-to-charge ratio is $57,000. Figure II shows Rheos hospitalization charges from one implant at one hospital site involved in the study. If you add these charges to the $57,000 charge for the device, the total charges for the hospitalization period are approximately $65,000, which falls within the 50th percentile of charges for DRG 108.

**Figure I – National Charge Data for DRG 8 and DRG 108**

| Charge data* | 25% Percentile | 50% Percentile | 75% Percentile |
|---|---|---|---|
| **DRG 8** | $8150 | $14,966 | $28,308 |
| **DRG 108** | $37,521 | $60,599 | $103,048 |

*Charge data from Solucient (2003 MedPar)

**Figure II – One Rheos Patient Charge Data**

| | |
|---|---|
| Med Surgery-2 Bed | $1,520.00 |
| Pharmacy | $78.85 |
| Sterile Supply | $1,181.09 |
| X-Ray Chest | $247.00 |
| Or Services | $4,857.00 |
| Anesthesia | $275.00 |
| Drugs-Detail | $51.09 |
| Drugs-Oral | $71.27 |
| Recovery Room | $233.00 |
| **Total Charges** | **$8,514.50** |

Drug refractory hypertension is a difficult and costly issue for many Medicare beneficiaries. The expectation for the Rheos System is that it will help reduce blood pressure in patients suffering from this disorder. Reduction of blood pressure is associated with reductions in related co-morbidities, improved quality of life and decreased healthcare costs. Medicare beneficiaries should have access to this technology and the technology should be tested on Medicare aged patients. However, without adequate reimbursement, patient access may be an issue.

CVRx urges CMS to reconsider the DRG classification for ICD-9-CM code 86.96 to DRG 108, which more closely approximates the cost of the procedure and device. I thank you for your consideration of this issue and look forward to working with CMS to ensure Medicare beneficiaries have access to this technology.

Sincerely,

Robert S. Kieval

President and CEO

CVRx, Inc. 10900 73rd Avenue North, Suite 116, Maple Grove, MN 55369 Phone (763) 416-2840 Fax (763) 416-2841 www.cvrx.com

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# Franciscan Skemp

*Mayo Health System*

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W/Bd

June 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Physical Address:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam:

RE: Wage Index

In reviewing the IPPS Proposed Rule dated May 4, 2005, we have discovered a change in Computation of the Proposed FY 2006 Unadjusted Wage Index that we oppose. On page 23372 and 23373 is a description of the computation of the unadjusted wage index. Section F., Step 4 describes the formulas for allocating overhead salaries and wage related costs to excluded areas for removal from the wage index. This formula has been used for several years. However, there is a change in the formula in the Proposed Rule FY2006 that is not explained in the text:

> FRVol.70, No. 85 page 23373
> "Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, **8, and 8.01**);"

The change in the formula reflects the addition of lines 8 and 8.01 to the denominator of the formula, thus lowering the denominator of the equation by the embedded subtraction from line 1, and increasing the ratio of overhead to revised hours. The higher ratio increases the amount of wage related costs removed from the wage index for excluded areas. The formula reported in the IPPS Final Rule dated August 11, 2004 reads as follows:

700 West Avenue South, La Crosse, WI 54601-4796
Phone 608-785-0940

FRVol.69, No. 154 page 49050
"Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7)"

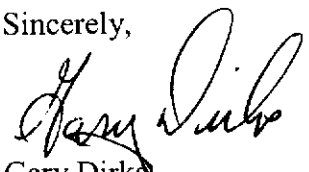
Thus, lines 8 and 8.01 do not appear in the denominator of the equation in the IPPS Final Rule for FY2005.

This change is not explained in the text of the IPPS Proposed Rule for FY2006. No impact study has been performed for the proposed change, which will particularly affect CBSA's with hospitals that have a large component of excluded area salaries.

This proposed change will have a negative effect of 4.3 percentage points on the wage index of the La Crosse, Wisconsin CBSA ( number 29100 ) where our hospital is located.

We oppose the change in the Computation of the Proposed FY2006 Unadjusted Wage Index on the grounds that it was unexplained in the text of the Proposed Rule, it has a negative impact on the majority of our State, and it is inconsistent with the formula as it was applied in prior years.

Sincerely,



Gary Dirks
Reimbursement Specialist
Franciscan Skemp Medical Center

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CAH Reloc

June 21, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1500-P
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**RE: CMS-1500-P, Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates; Proposed Rule.**

Dear Dr. McClellan:

Catholic Health Initiatives (CHI) appreciates the opportunity to comment on the Fiscal Year 2006 Hospital Inpatient Prospective Payment System (PPS) proposed rule. CHI operates 61 community hospitals in 17 states, including 15 Critical Access Hospitals (CAHs).

While CHI supports many of the provisions in the proposed rule, we are very concerned about proposals to dramatically expand the post-acute transfer policy and to prevent CAHs with necessary provider status from relocating.

## EXPANSION OF POST-ACUTE CARE TRANSFER POLICY

CHI strongly opposes the proposed relaxation of the criteria for including a DRG within the post-acute care transfer policy. The Centers for Medicare and Medicaid Services (CMS) raises the possibility of expanding the transfer policy from 30 Diagnosis Related Groups (DRGs) to either 231 DRGs or all DRGs.

Under the transfer policy, a hospital is paid a per diem rate, rather than the full DRG amount, if a patient is discharged to a post-acute setting (or home health within three days) and the hospital length of stay is at least one day less than the national average.

Expansion of the transfer policy to most or all DRGs undermines the basic principles, promises and objectives of the Medicare Prospective Payment System (PPS). PPS is based on a system of averages with gains of shorter than average stays offsetting losses of longer than average stays. The PPS system creates incentives for efficiency and reduction of unnecessary inpatient days.

The incentives of PPS would be reversed by a massive expansion of the transfer policy. The proposed expansion would undermine clinical decision-making, penalize hospitals for providing efficient care and create incentives to retain inpatients longer.

These arbitrary changes to the criteria for applying the transfer policy appear designed to obtain budget savings (in excess of $880 million in FY 2006), not to ensure that patients receive the right care in the right setting at the right time. CMS has not provided a scientific, clinically sound basis for setting these criteria, nor has it justified how these criteria satisfy congressional intent that the transfer policy be focused on those DRGs with a high volume of discharges to post-acute care and a disproportionate use of post-discharge services.

**The proposed expansion of the post-acute care transfer policy is not in the best interest of patients or providers. It is contrary to the intent of Medicare PPS, lacks scientific justification, and appears driven by budgetary goals rather than the desire to provide appropriate care to Medicare beneficiaries. This provision should be withdrawn in the final rule.**

## CRITICAL ACCESS HOSPITAL "NECESSARY PROVIDER" RELOCATIONS

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) terminates, effective January 1, 2006, a state's authority to allow a hospital closer than 35 miles to another hospital (or 15 miles in mountainous areas) to obtain CAH status by designating it as a "necessary provider." However, Congress clearly intended that CAHs designated as necessary providers by states before January 1, 2006 would be allowed to continue their CAH status.

In the proposed rule, CMS has invented restrictions that would cause a necessary provider to lose its CAH status if it builds a needed replacement facilities on a different site, even though it continues to serve the same community. This proposed rule violates congressional intent to continue the CAH status of necessary providers after the expiration of the state waiver authority.

A necessary provider would lose its CAH status if it rebuilt anywhere except on its existing site (or contiguous property purchased by December 8, 2003) unless the new hospital was

"under development" as of December 8, 2003 and an application for relocation had been submitted to the state agency prior to January 1, 2006. These date restrictions are unrealistic, unreasonable and not required by the MMA.

Many CAHs are housed in deteriorating, older buildings that need to be replaced in the coming years to improve patient safety and quality of care. The payment improvements for CAHs included in MMA finally provided some financial stability that allows these vulnerable hospitals to begin thinking about replacing their aging plants. Very few CAHs had these plans underway by December 8, 2003 or would be in a position to submit a relocation application to the state by January 1, 2006.

Rebuilding on existing or adjacent sites is not always an option. In addition to the disruption to patient care caused by construction at the existing hospital, a CAH may be landlocked where it is and have no choice but to move to meet the health care needs of its community. CAHs may need to move to new sites to be closer to highways, connect to municipal water and sewer, modernize telecommunications to support health information technology, and improve patient care delivery.

CHI currently operates 15 CAHs, several of which obtained their critical access status through state designation as "necessary providers". Continuation of these hospitals is vital to the rural communities and individuals they serve. Our Lady of the Way Hospital in Martin, Kentucky, is a prime example of the problems created by the proposed rule's deadlines.

Our Lady of the Way Hospital serves an impoverished, mountainous area of eastern Kentucky. Floyd County is one of the poorest counties in Kentucky with 25.3% of the population living in poverty, according to the most recent Census report. Median household income in Floyd County is $21,168, compared to $41,994 for the rest of the United States. This small, critical access facility operates six rural health clinics and provides more than $6 million a year in charity care -- 38% of the hospital's net patient services revenue -- to meet the health care needs of area residents. The cost-based reimbursement available through CAH status helps to sustain this needed facility.

Our Lady of the Way Hospital is in a landlocked, aging building that sits adjacent to the downtown area of Martin -- near the river. The river frequently floods the town, so the U.S. Army Corps of Engineers will be moving much of the downtown to a site higher up the mountain as part of a flood control project. The hospital and town leadership are hoping to obtain a site for the new hospital at the new town center but no decisions have been finalized. The hospital fell just outside of the floodplain even though its parking lot floods.

This is a hospital that is vital to the economic health of the town of Martin and to meeting the health care needs of individuals, particularly the elderly, with limited or no means of transportation to more distant facilities. However, Our Lady of the Way Hospital could not

meet the requirements of the proposed rule to have had its construction plans "under development" by December 8, 2003 or to submit a relocation plan to the state by January 1, 2006.

CMS should not, as proposed, consider hospitals that have moved a few miles from their current location as having ceased business and reopened as new providers. If a CAH designated as a necessary provider continues to serve the same communities, it should not be penalized for moving a few miles down the road to better meet the health care needs of its patients. If CMS is concerned that grandfathered CAHs could move to new markets without seeking new CAH approval, the proposed criteria for serving the same population with the same staff and providing the same services should be sufficient. However, any criteria should accommodate changes in demographics, the practice of medicine and community needs over time.

**Grandfathered necessary provider CAHs should be allowed to relocate as needed to increase efficiency, improve care and meet the health care needs of their communities. CMS should remove all construction plan deadlines from any criteria used to determine continued CAH status for grandfathered necessary providers who relocate.**

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Kevin E. Lofton

Kevin E. Lofton
President and Chief Executive Officer

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JUN 24 2005
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Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1500-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

*RE: CMS-1500-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule.*

Dear Dr. McClellan:

On behalf of the American Hospital Association's (AHA) 4,800 member hospitals, health care systems and other health care organizations and 33,000 individual members, we appreciate the opportunity to submit comments on the fiscal year (FY) 2006 inpatient prospective payment system (PPS) proposed rule.

While the AHA supports many of the proposed rule's provisions, we are particularly concerned about the potential underestimation of the market basket, the proposed expansion of the post-acute care transfer policy, the increase in the outlier fixed-loss threshold and the potential restrictions on the relocation of critical access hospitals (CAHs) with necessary provider status.

Current law sets the FY 2006 inpatient PPS update for hospitals at the rate of increase in the market basket, now estimated at 3.2 percent. Legislative and proposed regulatory changes, however, along with technical adjustments to ensure budget neutrality would result in a proposed average per case payment increase of only 2.5 percent. At the same time, the current estimates of the actual market basket increase for FY 2005 is 4.1 percent. We are concerned that CMS is dramatically underestimating the market basket for FY 2006. **We request that CMS review and revise the methodology used to determine the projected FY 2006 market basket.**

In 2003, 54 percent of hospitals had negative Medicare inpatient margins and one out of every three hospitals was losing money overall. Hospitals cannot continue to receive actual updates that are less than the rate of hospital inflation. **We will continue to urge Congress to provide adequate Medicare reimbursement to hospitals. And in our comments on this proposed rule, we also encourage CMS to make changes that would prevent further decline in Medicare payments.**

We are tremendously disappointed that the rule contains a proposal to further expand the post-acute care transfer policy, which would reduce hospital payments by nearly $900 million in FY 2006 alone. This policy is not in the best interest of patients or caregivers. It undermines clinical decision-making and penalizes hospitals for providing the right care at the right time and in the right setting. **This policy must be withdrawn.**

We are concerned that CMS is proposing to increase the outlier fixed-loss threshold despite the fact that CMS did not fully spend the 5.1 percent of funds set aside for such payments in FY 2005. Using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. **Instead, the AHA recommends a methodology that incorporates both cost inflation and charge inflation. The use of more than one indicator will make the threshold calculation more accurate and reliable.**

A state's authority to grant necessary provider status, and thus waive the distance requirement under the CAH program, expires January 1, 2006. However, the Medicare Modernization Act includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS' proposed rule would essentially bar necessary providers from ever rebuilding more than 250 yards from their current location. Appropriate and necessary relocations that will undoubtedly result in higher quality care, better patient outcomes and more efficient service should be allowed. **We urge CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care and meet the needs of their communities.**

We have enclosed detailed comments regarding CMS' proposed changes to the inpatient payment system. The AHA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about our remarks, please feel free to contact me or Danielle Lloyd, senior associate director for policy, at (202) 626-2340.

Sincerely,

Rick Pollack
Executive Vice President

**American Hospital Association**
**Detailed Comments on the**
**Proposed Rule for FY 2006 Inpatient Prospective Payment System**

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## Hospital Market Basket

**Market Basket Projection.** The hospital payment update is based on a market basket factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish inpatient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate inflationary update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For seven of the last eight years, the market basket projection has been lower than the actual increase (see attachment). While the market basket was overestimated for a number of years prior to that time, a methodology change was made in 1998 that appears to have overcorrected for the previous underestimations. For example, the actual increase in FY 2003 was 3.9 percent while the projected increase was 3.5 percent. In FY 2004 the actual increase was 3.8 percent compared to a 3.4 percent projection. CMS reports that, based on the most recent data, the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. We are concerned that the methods used to project the market basket increase are flawed and fail to provide a reliable estimate of hospital cost increases. Given a 4.1 percent cost increase for FY 2005, a projected FY 2006 increase of 3.2 percent does not seem reasonable. **We request that CMS review the methodology that was used to determine the projected FY 2005 market basket and revise it for the FY 2006 projection. We also urge CMS to make the details of the calculation public.**

**Blood and Blood Products Category.** In the proposed rule, CMS proposes to remove the blood and blood products category from the market basket and instead include those costs in the miscellaneous products category. CMS believes that the Bureau of Labor Statistics (BLS) Producer Price Index (PPI) for blood and derivatives "may not be consistent with the trends in blood costs faced by hospitals," and that "the PPI for finished goods minus food and energy moves most like the recent blood cost and price trends." We urge CMS to publish the data upon which this judgment is based.

The AHA appreciates CMS' recognition that the current BLS PPI for blood and derivatives is not capturing the increasing price trends for the blood products most commonly used by hospitals. While we support CMS' proposal to include blood and blood product costs in the miscellaneous products category, we support it only as a temporary measure until a more appropriate blood and blood products PPI can be developed by BLS. We strongly encourage CMS to work with BLS as they proceed in their stated intention to add the Blood and Organ Banks, North American Industry Classification System industry code 621991 to the BLS PPI program. We further urge CMS to work with BLS to ensure that:

- the key, high volume blood products used in transfusion medicine be included in the PPI survey – especially red blood cells (with or without leukoreduction), single donor platelets, whole blood derived platelets (random donor, with or without leukoreduction), and fresh frozen plasma and plasma; and,

- the costs associated with ongoing blood testing and processing should be included as price changes in the new PPI, since these procedures are required either by federal regulation, voluntary accrediting agencies or as standard of care to protect the public's health and safety and to ensure that the all blood collected in the country meets the same safety standards.

The goal should be supporting the development of a PPI index that tracks the price of a safe unit of blood over time.

## Hospital Quality Data

A hospital qualifies for its full Medicare market basket update if CMS determines the hospital has submitted data on the 10 specific measures of care for heart attack, heart failure and pneumonia that were the starter set for the Hospital Quality Alliance (HQA). The proposed rule includes several requirements for purposes of receiving the full market basket update. These requirements are: the hospital's continuous submission of quarterly data on the 10 measures, the submission of the data by May 15, 2005 for patients discharged through the fourth quarter of 2004; and the validation of the hospital's third quarter 2004 data.

To pass validation, the hospital must send copies of the relevant medical record information from five patient records chosen at random from among those on whom the hospital has submitted data to the Quality Improvement Organization (QIO) warehouse. CMS has contracted with an organization that will re-abstract all of the required data from the five records. If there is at least an 80 percent agreement between the information that the contractor has abstracted and the information the hospital abstracted for all of the measures that are applicable to those patients, then the hospital will have passed validation. If not, then the contractor will compare only those data elements that are required for the 10 measures included in the Medicare Modernization Act (MMA). If there is at least an 80 percent agreement on those required elements, then the hospital will have passed validation. If the hospital does not pass validation, it can appeal the results of the contractor's work to the contractor. The state's QIO will review and recommend to the contractor a disposition of the appeal. The contractor will reassess the hospital's submission in light of this additional information. Finally, if the hospital is unsuccessful in its appeal, it can ask that its fourth quarter data be used as well to determine validation. The hospital will have to submit the five randomly selected charts from its fourth quarter discharges by August 1, which is ahead of the normal schedule, and the contractor will use both the third and fourth quarter charts to determine if the data validate at least 80 percent of the time.

The AHA strongly supports the need for validation of the data that are submitted for the HQA. Validation is helpful in assuring that all information is being collected and processed similarly so that the publicly reported data create a reliable picture of the quality of care provided in each participating hospital. However, the law only calls for the submission of the data for hospitals to qualify to receive the full payment update. We believe that Congress recognized that taking submitted data and turning it into information that could be publicly reported is a process, and that there could be imperfections in that process. In linking payment to the submission of data, Congress suggested that hospital payments should not be held hostage to CMS or its contractors being able to correctly carry out the processing of the hospital data.

To date, there is enough evidence of flaws in the validation process to suggest that passing validation should not be a criterion for receiving the full Medicare market basket update. The validation process is sufficiently flawed that when it identifies a problem, one can only conclude that there is a difference between the information the hospital submitted and the data the contractor abstracted. No assumption can be made about which organization has correctly abstracted the data from the medical records. There have been numerous problems including logistical issues such as failure to get the request for the five files into the hands of a responsible authority at the hospital. In addition, data collection issues have arisen such as the misalignment of the data abstraction instructions hospitals were allowed to use and the instructions that the contractor had to adhere to in re-abstracting the data. Furthermore, processing issues have occurred such as the fact that hospitals have submitted appeals indicating why their data submissions were correct and the contractor's re-abstractions were incorrect, have had their QIOs verify to the contractor that the hospitals have correctly submitted the data, and had their appeals turned down without explanation. We have begun to collect information from hospitals about the problems with the validation process so that we can work with CMS to correct the validation process to ensure its accuracy and reliability.

**However, until the validation process is reliable, the AHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update. CMS' validation process is currently unreliable and needs improvement before it is used in determining which hospitals receive full updates.**

## Labor-Related Share

The MMA required CMS to update the inpatient PPS market basket at least once every five years. CMS proposes to update it every four years, beginning with rebasing and revising the market basket for FY 2006. For FY 2003, CMS rebased the market basket using 1997 data; however, CMS continued to calculate the labor-related share based on the 1992 data. The 1997 data would have raised the labor-related share to 72.5 percent from 71.1 percent, but there was concern at the time that the increase would hurt rural facilities that primarily have area wage indexes (AWIs) below 1.0. CMS cited the need to conduct additional analyses in deciding to leave the labor-related share at the 1992-based 71.1 percent. Shortly after, Congress included in the MMA a provision that held hospitals with a wage index below 1.0 at a 62 percent labor-related share.

For FY 2006, CMS is proposing to reduce the labor-related share from 71.1 percent to 69.7 percent due to the use of more recent data and the removal of postage from the labor-related share. This proposed change, if adopted, would adversely affect hospitals with an AWI greater than 1.0. The labor share for hospitals with AWIs less than 1.0 will remain at 62 percent as specified in the MMA. This change would be applied in a budget neutral manner by increasing the standardized amount for all hospitals.

We are concerned about CMS making any changes to the calculation of the labor-related share devoid of a broader plan to refine the methodology. Given that CMS was unable to discover an alternative methodology that is accurate, reliable and reasonably easy to apply, the AHA believes CMS should leave the labor-related share at 71.1 percent.

In particular, we are concerned about the large drop in the other labor-intensive services category (landscaping, protective services, laundry, etc.). We urge CMS to investigate this drop and whether it is a result of a flaw in the methodology. For instance, an inappropriately low-growth factor could cause an improper category weight and the underestimation of the market basket.

We also are concerned about the removal of postage from the labor-related categories. CMS' 2003 assertion that additional analyses are needed still stands today. The AHA believes that CMS should continue to consider this category labor-related until a broader look at the calculation of the labor-related share is taken. For example, another item that CMS should consider redesignating as a labor-related cost is professional liability insurance. These costs are wage-related - they are included in the wage index - and locally determined. However, because CMS has not recommended a full and thorough alternative approach to calculating the labor-related share, the agency should not alter the labor-related share.

CMS' proposed change will have a detrimental affect on all high-wage area hospitals while diverting funds back to low-wage hospitals that have already been protected through the MMA. **The AHA urges CMS to leave the labor-related share at 71.1 percent for FY 2006 and recommends that CMS continue investigating alternative methodologies for computing the labor-related share.**

## Post-Acute Care Transfers

Medicare patients in certain diagnosis-related groups (DRGs) who are discharged to a post-acute care setting – such as rehabilitation hospitals and units, long-term care hospitals, or skilled nursing facilities – or are discharged within three days to home health services are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount.

The AHA is very disappointed with CMS' continued effort to expand the post-acute care transfer policy. In the proposed rule, CMS discusses the possibility of expanding the policy from 30 DRGs to either 223 DRGs (later revised to 231) or all DRGs. Specifically, CMS proposes to expand the application of the post-acute care transfer policy to any DRG that meets the following criteria:

- At least 2,000 discharges to post-acute care;
- At least 20 percent of its discharges are to post-acute care;
- At least 10 percent of its discharges to post-acute care occur before the geometric mean length of stay for the DRG;
- A geometric mean length of stay of at least three days; and
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

The AHA is frustrated with CMS' repeated attempts to find the right criteria to achieve the desired budget results, rather than the right policy regardless of its budget implications. The AHA conducted analyses to better understand the impact of the proposals in the rule as well as the revised list of DRGs potentially subject to the policy. This misguided approach to expand

the transfer policy to 231 DRGs will have a devastating impact on hospitals by reducing overall payments by an estimated $894 million in FY 2006 alone when the effects on disproportionate share hospital (DSH), indirect medical education (IME), capital and outliers payments are considered. This is particularly problematic given that more than 50 percent of hospitals are already losing money treating Medicare inpatients and overall Medicare margins have declined every year since 1997 to an estimated *negative* 1.9 percent.

**The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system.** The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

**The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place.** The policy hurts hospitals that make sound clinical judgments about the best setting of care for patients – and this setting is often outside of the hospital's four walls. Hospitals should not be penalized for greater than average efficiency. Particularly, facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients are disproportionately penalized.

**The post-acute transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist.** When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by the AHA and others show that the majority of patients who use post-acute care have <u>longer</u> – not shorter – hospital stays than patients that don't use post-acute care, demonstrating that these patients are truly "sicker" and in need of additional care. In FY 2004, for instance, patients that were not transferred to post-acute care had an average length of stay of 4.93 days, while those who did receive post-acute care had an average length or stay of 7.51 days. If the agency is concerned about premature discharges, then we recommend it focus on improving the quality review process rather than further expand the transfer provision.

Section 1886(d)(5)(J) of the Social Security Act directs CMS to focus on those DRGs that have a high volume of discharges to post-acute care and a disproportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have *disproportionate* use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to post-acute care in FY 2004. Clearly 88 percent of DRGs with *any* post-acute care use cannot have *disproportionate* use. Furthermore, CMS is also capturing DRGs that are not at all *high-volume*. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2070 discharges to post-acute care as compared to DRG 544 (major joint replacement or reattachment of lower extremity) 349,085 discharges to post-acute

care. It cannot be argued that while DRG 473 does not have a *high-volume* of discharges to post-acute care, it still has *disproportionate* use. Only 22.7 percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. **CMS' current criteria cast far too wide of a net and capture far more DRGs than authorized by current law.**

CMS has argued that the post-acute care transfer policy levels the playing field for rural hospitals that do not have comparable access to post-acute care. The AHA challenges this assertion. We compared the rates of discharge to post-acute care for the DRGs to which the post-acute care transfer policy would apply using the 2004 MedPAR data and found that urban hospitals discharged patients before the average length of stay 10.6 percent of the time, while rural hospitals discharged patients before the average length of stay 9.2 percent of the time. This demonstrates that the transfer policy will have fundamentally the same negative affect on rural hospitals as urban. Moreover, 4.5 percent of discharges from rural hospitals are to other acute-care facilities, while only 1.6 percent of discharges at urban hospitals are to other acute-care facilities. It is likely that some of the patients discharged from rural hospitals are then admitted at urban hospitals that then in turn discharge patients to post-acute care. **Thus, rural patients have essentially the same access to post-acute care as their urban counterparts. The policy does not create equity; rather it harms all hospitals and the patients they serve.**

Furthermore, transfer cases are weighted at less than 100 percent for the purpose of computing DRG weights. The substitute weight is the share of the full DRG payment that is represented by the transfer payment. This has the effect of maintaining the DRG weight at an artificially high level. By doing this, the natural weighting process is hampered and the relative nature of the weights is distorted.

**The AHA objects to an expansion of the post-acute care transfer policy, which is not in the best interests of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. This provision must be withdrawn in the final rule.**

## Operating Payment Rates

**Outlier Payments.** The rule proposes to establish a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including IME, DSH, and new technology payments, plus $26,675. While this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, we remain very concerned that the threshold is too high. CMS states in the proposed rule that actual outlier payments for 2005 are estimated to be 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments and that the payments in 2004 were 1.6 percentage points lower than the funds withheld.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2003 in combination with the first quarter of 2004 to the last quarter of 2004 in combination with the first quarter of 2005 to establish an average rate of increase. This results in an 8.65 percent rate of change over one year or 18.04 percent over two years.

The AHA appreciates that CMS is proposing this methodology in an effort to avoid using data prior to the major changes in the outlier policy. **However, using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. The AHA strongly opposes using this methodology to estimate the outlier threshold.** Thus, the AHA conducted a series of analyses to identify a more appropriate methodology. Below we put forth for CMS' consideration a methodology that incorporates both *cost* inflation and *charge* inflation. The use of more than one indicator may make the threshold calculation more accurate and reliable.

First, we inflated 2004 charges by 18.04 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, we used the CCRs from the March 31, 2005 HCRIS release. In addition, we accounted for the nine-month lag from the end of a cost reporting period until the fiscal intermediary is able to update the CCR. We accomplished this by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2006 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,756 matched hospitals for periods beginning in federal FYs 2001, 2002 and 2003. All three costs reports were available for each hospital from the recent update of HCRIS. The 2001-2003 aggregate annual rate of increase in the cost per discharge for these hospitals was 6.57 percent[1]. This cost inflation factor and the CMS charge inflation factor of 8.65 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for federal FY 2006 outlier payments. **The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,050.**

The AHA strongly urges CMS to adopt this methodology. We estimate that the fixed-loss threshold to achieve 5.1 percent in FY 2005 should have been set at $21,640 as compared to the $25,800 actually utilized. CMS underspent the funds set aside for outliers by an estimated $610 million in FY 2005 and $1.3 billion in FY 2004. **If CMS leaves the threshold at $26,675, rather than dropping it to $24,050, we believe that CMS will again underspend by at least $510 million. We urge CMS to adopt our recommended methodology to lower the outlier threshold.** We would be happy to provide CMS with additional information on this analysis.

## Occupational Mix Adjustment

**FY 2006 Adjustment.** The occupational mix adjustment to the wage index is intended to control for the effect of hospitals' employment choices – such as the use of registered nurses versus licensed practical nurses or the employment of physicians – rather than geographic differences in the costs of labor. CMS proposes no changes to the methodology used in FY 2005 in the proposed rule, and indicates that nearly one-third of rural areas and more than half of urban areas would see a decrease in their wage index as a result of this adjustment. Given the potential financial impact of a full adjustment on hospitals, concerns regarding the data, and

1 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 1,881 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2005 HCRIS update.

changes in the regulatory environment such as state-mandated minimum nurse staffing ratios, CMS is proposing to again limit the application of the occupational mix adjustment to 10 percent of the wage index. **Due to the concerns CMS expresses in the proposed rule, the AHA is supportive of this moderated implementation of the occupational mix adjustment.**

**Future Data Collection.** The AHA urges CMS to release a proposed survey for comment as soon as possible to ensure accurate and reliable data. We urge CMS to allow for an appropriate amount of time to develop the survey, provide clear instructions, adapt the systems, collect the data, prepare the survey responses, audit the data, correct the data, and calculate the adjustment. Given that CMS must have the adjustment ready for the FY 2008 adjustment (or the April 2007 proposed rule), **the AHA recommends that CMS release the proposed survey this summer to meet this timeframe and allow hospitals adequate time to prepare for the data collection and reporting.**

## Wage Index

**Wage Index Calculation Change.** The inpatient PPS proposed rule contained a change in the wage index calculation. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 in the *Federal Register*.

The change is in the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

i. Determine the ratio of overhead hours to revised hours.
ii. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step *i* by wage-related costs.
iii. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in the above step *i*. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step *i*, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

The AHA is concerned that CMS would make such a change to the calculation of the wage index without any discussion. We request that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers should be given an opportunity to comment on this revision to the methodology before it is implemented. The AHA believes that this methodological revision will have a significant impact on the wage indexes for some hospitals. **Accordingly, CMS should return to the established methodology and go through the full notice and comment process before making such a change. We further recommend that hospitals be given an opportunity to withdraw or reinstate their requests for geographic reclassification within 30 days of the publication of the final rule.**

**Commuting Data.** CMS should make available the hospital commuting data collected by the BLS and utilized by CMS in the out-commuting adjustment. While the data are supposed to be on the BLS Web site, we have been unable to locate it. This information will assist us in verifying the adjustment calculations and aid in our research of labor market areas.

## Out-Migration Adjustment

Hospitals that qualify for an out-migration adjustment and do not waive the application of the adjustment are not simultaneously entitled to reclassification pursuant to Sections 1886 (d)(8) or (d)(10). Because significant changes to the wage index took place in FY 2005, CMS allowed hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the FY 2005 final rule. By doing so, CMS acknowledged that changes made between the proposed and final rules could affect whether a hospital was better off accepting the out-migration adjustment or whether it would be more advantageous for a hospital to waive the out-migration adjustment and pursue geographic reclassification.

Although the changes to the wage index are not as extensive for FY 2006, there is still a likelihood that revisions made between the proposed and final rules may impact a hospital's choice of whether to accept the out-migration adjustment or to apply for geographic reclassification. **Thus, the AHA requests that CMS implement a policy similar to last year's and allow hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the final rule.**

The AHA also notes that for FY 2006, the second year of the out-migration adjustment, CMS is applying adjustments that are identical in amount to the adjustments given in FY 2005. It appears that hospitals will receive the same adjustment in each of the three years of eligibility for the out-migration adjustment. The AHA does not believe that the governing statute, Section 505 of the MMA, requires that the adjustments be identical for all three years. The statute only requires that the adjustment be granted for a three-year period.

It is not logical or fair to freeze the amount of the adjustment for three years. Because of changes in the wage index each year, some hospitals will be receiving out-migration adjustments even though the wage index for their geographic area is now higher than the wage index for the county to which their residents are commuting. Likewise, there may be hospitals that would be entitled to a higher out-migration adjustment if it were recalculated based on the new wage indexes for FY 2006. The three-year eligibility period for the out-migration adjustment is similar to the three-year eligibility period for geographic reclassifications, but the wage indexes for the latter change each year despite the guaranteed three-year reclassification. **The AHA recommends that CMS revise its policy so that the out-migration adjustment will be recalculated each year based on updated wage data and the new wage indexes.**

## Hospital Redesignations and Reclassifications

**Urban Hospitals Redesignated as Rural.** In adopting the CBSAs, a small number of hospitals that were classified as urban in FY 2004 became classified as rural in FY 2005. Because moving from a metropolitan statistical area (MSA) to the rural statewide average would have resulted in a significant decline in these hospitals' wage indexes, CMS implemented a three-year transition period (FYs 2005 - 2007). The AHA supports the continued transition for these hospitals to give them the opportunity and time to reclassify.

**Hold-Harmless for Certain Urban Hospitals Redesignated as Rural.** Last year, CMS discovered an instance where the approved redesignation of an urban hospital as rural resulted in the hospital's data adversely affecting the rural wage index. To address this concern, CMS

proposes for FY 2006 to apply its hold-harmless rule that currently applies when rural hospitals are reclassified as urban to situations where urban hospitals are reclassified as rural. Thus, wage data of an urban hospital reclassifying into a rural area would be included in the rural area's wage index, if including the urban hospital's data increases the wage index of the rural area. Otherwise the wage data are excluded. **The AHA supports this proposal to apply consistent hold-harmless provisions to both urban and rural areas for the purpose of geographic reclassifications.**

**Urban Critical Access Hospitals Redesignated as Rural.** The AHA requests CMS clarify the treatment of hospitals that are located in urban areas and apply for reclassification as rural. According to CMS statements in the proposed rule, "a hospital that is granted redesignation under section 1886(d)(8)(E) of the Social Security Act as added by section 401 BBA, is treated as a rural hospital for all purposes of payment under the inpatient PPS, including the standardized amount, wage index and disproportionate share calculations as of the effective date of the redesignation." CMS makes this statement in the context of a proposed policy change on the wage index in an effort "to promote consistency, equity and to simplify our rules with respect to how we construct the wage indexes of rural and urban areas when hospital redesignations occur."

However, this same consistency in policy has not occurred when these redesignations occur for critical access hospitals (CAHs) that are located in urban areas as of October 1, 2004 as a result of the use of the 2000 census data. Although the regulations were changed last fiscal year to allow CAHs in this situation to be temporarily reclassified as being located in a rural areas, CMS has not provided the same affirmative direction for CAHs in terms of treatment as rural for all purposes of Medicare payment. For example, the fiscal intermediary in one state has revoked the certified registered nurse anesthetists (CRNA) pass-through status for CAHs located in metropolitan areas as a result of the census change, citing the fact they are considered urban. Further, the fiscal intermediary has indicated the rural designation under section 1886(d) is only for provisions of 1886(d) and since the CRNA pass-through provision is outside of this section, the rural determination does not apply.

However, in examining the authority for the CRNA pass-through at 42 USCA §1395k note, the rural definition references section 1886(d) of the Social Security Act. In section 1886(d)(2)(D)(ii), "urban area" is defined as an area within a Metropolitan Statistical Area and "rural area" is defined as any area outside such an area or similar area. However, a further section of 1886(d) at 1886(d)(8)(E) allows a hospital to be treated as being located in a rural area if it meets the qualifications in this section. Since the annotated code refers broadly to section 1886(d), the rural determination made under 1886(d)(8)(E) does apply for the purposes of the CRNA pass-through as directed by the code.

**The AHA urges CMS to make an affirmative statement that all hospitals granted a redesignation should be treated rural for all purposes of Medicare payment.**

## Geographic Reclassifications

**Urban Group Reclassifications.** The AHA is pleased that CMS is proposing to allow counties that are included in a Combined Statistical Area (CSA) to reclassify to a contiguous metropolitan

division of the CSA using the 2000 standards. We believe that this is an appropriate policy approach and acknowledges the realities of areas that are just outside major metropolitan areas and must meet the competitive salary scales in order to attract and retain competent health care professionals.

The AHA further urges CMS to modify its policy to allow hospitals located in counties that are in the same Core Based Statistical Area (CBSA), as well as CSA, as the county to which they seek redesignation to be considered to have met the proximity requirement. By failing to include CBSAs in the proximity criteria, CMS has excluded one group of hospitals, those located in Palm Beach County, Florida, from being able to reclassify to the Fort Lauderdale-Pompano Beach-Deerfield Beach division of the Miami CBSA. The AHA assumes that it was not the intention of CMS to exclude this one county group. Since CBSAs are actually more refined classifications than CSAs, we believes that inclusion of CBSAs in the proximity criteria would be consistent with CMS' policy goals to both transition to the new labor market area definitions and to protect hospitals from unintended unfavorable consequences.

In addition, the AHA is concerned that group reclassifications will be affected by the timing of section 508 of the MMA. In section 508 for instance, Ventura, California, Nassau Suffolk, New York and Providence, Rhode Island will all be prevented from reclassifying for 2007 because an individual hospital that is getting section 508 payments that is ineligible to reclassify. We do not believe that Congress intended for the section 508 hospitals to prevent group reclassifications. In addition, section 508 is not budget neutral, thus it would be inappropriate to encourage such hospitals to forgo the section 508 funding to join a group reclassification at the expense of all other hospitals. **The AHA urges CMS to allow section 508 hospitals to commit to a group reclassification and join after the section 508 funding expires.**

**Multi-Campus Hospitals.** Multi-campus hospitals have one provider number and thus one cost report. An individual campus cannot apply for reclassification, currently, because the wage data are not broken down by campus on the cost report. CMS proposes to allow individual campuses to complete the manual version of the S3 form in order to have the information necessary to reclassify. In addition, CMS suggests that the data from all campuses be used as a proxy for individual campuses that wish to reclassify for FY 2007 as a result of the labor market changes included in the FY 2005 final inpatient PPS rule and do not have the appropriate individual campus data.

The AHA believes that the use of the manual S3 would be appropriate to collect the necessary data. **However, this option should only be available for campuses that were redistricted into different MSAs as a result of the adoption of the 2000 census data. We further assert, that campuses should only be allowed to reclassify to an area where another one of the campuses is located.**

**Rural Urban Commuting Areas.** The Office of Rural Health Policy (ORHP) began using the rural-urban commuting areas (RUCAs) rather than updating the Goldsmith modification for defining rural areas. While we understand that CMS is simply updating its regulatory references in the proposed rule, the AHA is concerned with using RUCAs to define rural areas. Although the definition works for most areas of the country, there are some anomalies. **We urge CMS to**

**work with ORHP to rectify the problems in the methodology and ensure that rural areas are not inadvertently classified as urban.**

## New Technology Applications

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. Despite this, CMS is essentially proposing to reject all eight applications (six new and two re-evaluations) and only maintain payment for one currently approved technology. The AHA is concerned that CMS continues to resist approving new technologies for add-on payments. **The AHA also is disappointed that CMS did not propose to increase the marginal payment rate to 80 percent rather than 50 percent consistent with the outlier payment methodology, which it has the authority to do without reducing payments to other services.**

Moreover, we are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the committee language for the MMA, recommended that the Secretary of Health and Human Services (HHS) undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology as required under the Benefits Improvement and Protection Act of 2000.

To date, in spite of these recommendations, as well as the recommendations of several federal health care agencies and offices, and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that without a change to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. Additionally, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories was a

deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculosketal system, circulatory system, etc.) were available. The plan was to use up codes in chapter 00 first and then start populating chapter 17.

We have now reached the point where category 00 is full and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (like cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule. Without the publication of even a proposed rule, the prospect of being unable to recognize new major surgical procedures and entirely new medical technology is a certain grim reality.

**The AHA strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously.** HHS should take the necessary steps to avert this crisis and avoid the situation of being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. It is imperative that the rulemaking process starts immediately.

## DRG Reclassifications

In general, the AHA supports CMS' proposed changes to the DRG system, as the revisions appear rational given the data and information provided. However, we do have concerns about some of the proposals as detailed below.

**MDC 1 (Diseases and Disorders of the Nervous System) – Strokes.** CMS reviewed the possibility of creating a new DRG with a recommended title "Ischemic Stroke Treatment with a Reperfusion Agent." The data reviewed by CMS suggested that the average standardized charges for cases treated with a reperfusion agent are more than $16,000, or $10,000 higher than all other cases in DRGs 14 and 15, respectively. Although the data suggested that these patients are more expensive than all other stroke patients, CMS proposed not to make a change to the stroke DRGs because the conclusion was based on a small number of cases. CMS believed that the administration of tissue plasminogen activator (tPA) identified by ICD-9-CM procedure code 99.10 may be underreported because it currently does not affect DRG assignment.

**The AHA requests that CMS create a new DRG to recognize the additional resources associated with strokes and tPA administration even if the data analyzed did not have a large number of cases.**

While it may be true that code 99.10 is underreported because it currently does not affect DRG assignment, the number of patients meeting the clinical indications for receiving tPA administration is low. Published clinical data show that only 2 percent of patients with stroke receive intravenous tPA nationally (*Archives Neurology*, 2004, March; 61) and the rate among

community hospitals may be slightly less at 1.6 percent (*Stroke*, 2001 August; 32). These statistics are only slightly higher than the 1.16 percent rate found in CMS data for patients in DRG 14 without intracranial hemorrhage with code 99.10.

The effective administration of tPA requires that treatment be administered within three hours of onset of a stroke, and only after ruling out hemorrhagic stroke by computed tomography. Intravenous thrombolytic agents are not recommended when the time of stroke onset cannot be ascertained reliably, including strokes recognized on awakening. These indications significantly limit the number of patients eligible for tPA administration.

According to published clinical studies, administering tPA in clinical practice has proved very difficult. The biggest challenge is the ability to determine that symptom onset occurred less than three hours prior to the time of the tPA infusion. Patients need to be educated to recognize the symptoms of a stroke and to seek early treatment. Administration of tPA in stroke patients requires that the patient recognize that something is wrong, is transported to a hospital equipped to provide this therapy, undergoes a history and physical examination and CT scan, and has this scan read by a qualified radiologist—all within the three hours of initial onset of symptoms.

For all the clinical reasons noted above, it is unlikely that the number of stroke cases reported with code 99.10 will increase significantly in the near future. **Regardless, the additional resources required to treat these patients should be recognized with a new DRG.**

**Complication/Comorbidity List.** CMS has indicated that they are planning a comprehensive and systematic review of the complication/comorbidity (CC) list for the inpatient PPS rule for FY 2007. CMS considers this review to be consistent with the Medicare Payment Advisory Commission's (MedPAC) recommendation that CMS improve the DRG system to better recognize severity.

We applaud CMS' efforts to keep refining the DRG system to better recognize severity of illness, and the resources required to treat those illnesses. However, we believe that this is a temporary fix and a more refined DRG system can only be accomplished with more specific clinical classification systems, capable of painting a more complete picture of a patient's condition and the services provided to treat those conditions - namely ICD-10-CM and ICD-10-PCS. We strongly agree with CMS' assessment in the May 9, 2002 hospital inpatient PPS notice of proposed rulemaking, that ICD-10 is an improvement over ICD-9-CM and that it will provide greater specificity and detail. Thus, we again urge CMS to implement ICD-10.

Furthermore, we are concerned that CMS may not be evaluating all diagnoses and procedures that could possibly affect a patient's severity of illness and/or the resources utilized. The current DRG grouper only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the grouper to assign a DRG. While it is important for inpatient acute hospitals, it is even more crucial for long-term care hospitals (LTCHs) whose patients are medically complex and have multiple illnesses beyond the nine diagnoses allowed

by CMS. Moreover, a list of CCs qualifying for comorbidity adjustments for inpatient psychiatric facilities' services was only recently introduced under the new PPS. Thus, these hospitals have not historically utilized the software available to sort and rearrange secondary diagnosis codes so that all CCs possibly affecting the DRG grouping are prioritized.

**We urge CMS to modify the DRG grouper and instruct fiscal intermediaries to expand the number of diagnoses from nine to 25, and the number of procedures from six to 25, in order to include all reportable diagnoses and procedures in the DRG calculation.**

## MedPAC Recommendations

The MedPAC recommendations discussed in the proposed rule grew out of concern that limited-service providers were given an unfair advantage under the inpatient PPS. However, it is unclear how such changes will affect the remaining PPS hospitals. While the AHA supports refining the PPS, care should be taken in such an endeavor given that the majority of hospitals are losing money under the Medicare inpatient PPS. Therefore, the AHA urges CMS to proceed slowly and deliberately with extensive research as a foundation for any proposed changes.

## Critical Access Hospitals

**Rural Hospitals Redesignated as Urban.** One of the requirements for CAH designation is that the hospital must be located in or reclassified to a rural area. As a result of the most recent labor market changes, some counties that were previously considered rural were redesignated as urban. Per the MMA, a rural county that is adjacent to one or more urban counties is considered to be located in the urban MSA to which the greatest number of workers in the county commutes, if certain conditions are met. These are known as "Lugar counties." Thus, some CAHs are now located in Lugar counties and are unable to meet the rural location requirement, even though they were in full compliance at the time they were designated as critical access.

In response, CMS proposes that CAHs in counties that were designated Lugar counties effective October 1, 2004 because of the new labor market definitions will be allowed to maintain their CAH status until September 30, 2006. **The AHA supports the continued transition for these hospitals to give them the opportunity to reclassify.**

**Necessary Provider Status Relocations.** Currently, a governor may certify a hospital as a "necessary provider," which allows that hospital to become a CAH even if it fails to meet the distance requirement of being more than 35 miles (or 15 miles in mountainous areas or by secondary roads) away from a PPS hospital or another CAH. The MMA terminates a state's authority to grant necessary provider status as of January 1, 2006; however, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation.

The AHA believes that CMS is exceeding its authority and independently developing a policy that is in conflict with the law. The MMA clearly established the intent of Congress to exempt current facilities from the expiration of the necessary provider waiver. Yet, for FY 2006 and beyond, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing site or relocate onto a contiguous piece of property if it

was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area (HPSA) and remains in a HPSA);
- Serves the same community (75 percent of same population, 75 percent of same services, 75 percent of the same staff);
- Complies with the same conditions of participation; and
- Was "under development" as of December 8, 2003 using similar criteria as the specialty hospitals guidelines (architectural plans, financing, zoning, construction bids, etc).

The date restrictions proposed by CMS are unrealistic and unreasonable. December 8, 2003 is simply the date the MMA was signed into law and has no connection to a CAH relocation deadline in law. The ability of governors to newly approve necessary providers expires January 1, 2006, more than two years later than the date arbitrarily chosen by CMS for the relocation deadline. Regardless, the law expressly allows those existing providers to maintain their status after that date with no articulated restrictions. **Consequently, we insist that CMS remove the arbitrary date restrictions for relocations that have no basis in law.**

CAHs are often housed in old buildings that are in desperate need of renovations, but prior to converting, these facilities could not gain access to capital due to their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, not because of excessive profits, but because of the stability of Medicare reimbursements covering certain allowed costs. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or other essential upgrades. **Such improvements will undoubtedly result in higher quality care, better patient outcomes, and more efficient service.**

Many facilities need to, or choose to, rebuild on a new site to be closer to a highway, connect to municipal water and sewer, because of seismic safety concerns, or other reasons that again, will improve patient safety and the quality of care provided. In addition, many CAHs are landlocked with little or no room for expansion, thus they have no choice but to relocate if they must rebuild. **Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.**

The AHA believes CMS has gone too far in trying to paint hospitals that are moving a few miles from their current location as having ceased business and reopened as a *new provider.* This shows a general lack of knowledge about rural areas. These CAHs are integral to their communities and often one of the biggest employers. Moving down the road will not demonstrably change the population served. **We further assert that CMS automatically should consider any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.** We would not, for example, support the use of city limits as the measure of whether a hospital is rebuilding or relocating. In many areas, the city limits are a

political boundary that may not change regularly to reflect the changing population and may not be consistent with the health district boundaries. Moreover, it is difficult in many areas to find a large enough piece of land, possibly 40 acres, within the city limits and at an affordable price. Furthermore, one of the objectives of many relocating facilities is to move to the edge of town where EMS access is easier.

If a CAH moves further than five miles, and CMS is concerned about whether the same population is being served, then we would recommend an approach similar to the 75 percent test described earlier. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff, and providing 75 percent of the same services are warranted.

For instance, natural changes in demographics and the practice of medicine will occur over time that may necessitate a change in services when a hospital is rebuilt. Or, a greater reliance on new technology may limit the number or change the type of staff needed at a newly built facility. **Some flexibility in the measures is needed to allow for such expected changes in the needs of the community.**

Therefore, the AHA recommends that CMS expand its measures and alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show through a needs assessment that the change in services provided would be appropriate, then the test of 75 percent of the services should not need to be met. If a CAH has undertaken a cost comparison that shows that a new facility on another site would be less expensive than rebuilding on the current location, then only two other measures should need to be satisfied. **A combination of the criteria suggested would offer CAHs some flexibility and allow for the natural development and maturation of the CAH and the community.**

We also encourage CMS to consider special provisions for hospitals that are merging. Under these circumstances, the two hospitals may not be able to meet the criteria. In these cases, CMS should make determinations on a case-by-case basis. If the merger meets the needs of the communities, then CMS should consider it an appropriate and allowable relocation.

Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when counting the staff, how should the hospital ascertain if the staff would continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? Is the fact that you plan to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. **CAHs need clear expectations and advanced warning of the standards to which they will be held.**

CAHs are the sole providers of inpatient acute-care services in their communities and often outpatient and long-term care services. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. Thus, it is unlikely that

they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement there would be other hurdles, such as getting licensed for additional beds in certificate of need states or hiring additional staff to expand services when there are shortages in many areas that would need to be surmounted in an effort to build volume to survive under the PPS. For many of these CAHs, loss of their status would force them to close. **Given the role of these facilities in their communities, such closures would have devastating affects on rural health care access.**

**We urge CMS to rescind its overly restrictive relocation policy and allow necessary provider critical access hospitals to relocate as needed to improve the care and meet the needs of their communities. Instead, CMS should expand and use the criteria recommended above.**

**Pending Necessary Provider Status Applications.** The AHA is concerned about the hospitals that are currently in the process of converting to CAH status under the necessary provider program. We have heard reports from some states that the queue to be surveyed is growing and despite a hospital's best efforts and advanced planning, the survey to obtain the new provider number may not occur by January 1, 2006. It also is possible that the survey will occur, but the plan of correction will not be accepted by the deadline if one is needed. States have an enormous survey workload that is further exacerbated by Emergency Medical Treatment and Labor Act (EMTALA) surveys that take priority. **Providers that have gotten to the stage of requesting a survey in advance of the January 1, 2006 deadline, but are unable to get the state to complete the survey have clearly demonstrated a good faith effort and should be considered as meeting the deadline.**

## Low-Volume Hospital Payment Adjustment

Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per-case of low-volume hospitals. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges during the year. The rule proposes to maintain a 25 percent increase, the maximum allowable, in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS proposes to maintain its current policy, applying no payment increase. Only 10 hospitals currently are receiving this adjustment. **The AHA is concerned that CMS is ignoring congressional intent and denying a group of hospitals – those with over 200 discharges but less than 800 discharges – access to this necessary payment increase.**

## Rural Community Hospital Demonstration Program

Section 410 of the MMA requires CMS to conduct a demonstration program in rural areas where qualifying hospitals with fewer than 51 beds would receive cost reimbursement, rather than PPS payment, for inpatient acute care and swing-bed services for a five-year period. To satisfy the law's budget neutrality requirement, CMS proposes to offset inpatient PPS payments to other hospitals by $12.7 million. Given that the demonstration was clearly designed to provide higher payments to these facilities, **the AHA agrees that the law intended for the program to be budget neutral to the entire inpatient PPS rather than within the demonstration.**

## DSH Adjustment Data

Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. The AHA believes that this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine whether the data based on the federal fiscal year or their own fiscal year is advantageous. **The AHA supports CMS' plans to release a MedPAR limited data set for both SSI and Medicare.**

**The AHA, however, strongly objects to CMS' decision not to make available Medicaid information**. Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA states that the Secretary must arrange to provide information hospitals need to calculate the Medicare DSH payment formula. This same section in the version of the MMA passed by the House of Representatives states specifically that the Secretary is required to provide the information to hospitals so they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital field has brought this issue regarding the difficulty in obtaining Medicaid information from the states to CMS' attention for several years. Efforts were made through the Medicare Technical Advisory Group to find ways to remedy this problem. CMS then as now, continues to ignore this problem.

CMS states in the rule that it believes hospitals are best situated to provide and verify Medicaid eligibility information and that the mechanisms are currently in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting, and justifying the Medicaid days is problematic in many states. While some improvements have been made in the process for obtaining Medicaid eligibility and payment information from the states, there is still wide variation in the breadth of information provided as well as its accessibility and reliability. In addition, the information from the states still must be processed to match claims data with eligibility data and then manipulated to develop reports that are acceptable to the fiscal intermediary. This is a complex process that is time-consuming and labor intensive. As a result, hospitals often find it necessary to hire consultants that have the required expertise and computer programs. Moreover, the penetration of Medicaid managed care can add an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals.

**Therefore, the AHA recommends that CMS impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information. The AHA further recommends that CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state, and that the state make this information available to the providers and contractor audit staff.**

## Provider-Based Entities

**Rural Health Clinics.** CMS' proposed rule would add rural health clinics with 50 or more beds to the list of specific types of facilities and organizations for which determinations of provider-based status would not be made. **The AHA supports this change.**

**Neonatal Intensive Care Units.** The provider-based requirements were designed to prevent physician offices or clinics with little to no integration with a hospital from providing relatively low-level services and receiving the higher hospital-based Medicare outpatient rates. The 35-mile requirement was introduced as one of a number of measures of integration between a general-acute care facility's main campus and its provider-based entities. However, unlike general acute-care facilities, children's hospitals are fewer in number and tend to cover wider catchments areas. In the case of the provider-based neonatal intensive care units (NICUs) located in host hospitals described in the rule, there is no question of the level of services or integration with the parent hospital regardless of the distance to the parent hospital. The type of inpatient services provided requires specialized equipment, staff and support that the host hospital could not provide on its own.

We are currently aware of only one children's hospital that is providing such services through this model. While the off-campus NICUs meet all of the other provider-based criteria, they are more than 35-miles away from the main campus. However, the intent of these NICUs is to bring specialized services closer to the outlying areas that the parent hospital serves. Such small units are not profitable, but are still supported by the parent facility to meet the needs of an economically-impoverished and medically-underserved community that is largely rural.

Options one, three and four described in the rule are problematic. Option one, would simply expand the mileage limitation and create an additional blunt measure that does not fully account for the appropriate provision of crucial services in underserved areas. Option three, would require changes to each state's Medicaid plan, which would be difficult for individual hospitals to achieve. Option four, would require the NICUs to covert to hospital-within-hospitals, which is unrealistic for six-to-eight bed units that require the support of a full-service children's hospital. **The AHA believes that the best approach to address this problem and ensure access to these critical services in underserved areas is option two, which would exempt off-campus NICUs from only the distance limitation where all other provisions of the provider-based requirements under Sec. 413.65 are satisfied.**

## Graduate Medical Education

**Initial Residency Period.** Last year, CMS instituted a new policy for weighting the direct graduate medical education (GME) resident count for residents that pursue specialties requiring an initial year of broad-based training, such as anesthesiology. The new policy allows the initial residency period to be based on the period of board eligibility for the specialty, rather than the clinical-base year. CMS now further proposes to base the initial residency period on the period of board eligibility for the specialty when a resident matches directly to an "advanced program" without regard to fact that the resident did not match for an initial clinical base-year training program. This would allow hospitals to be paid an entire full-time equivalent (FTE), rather than half of an FTE for such residents until they are board eligible. **The AHA supports this change.**

**Affiliation Agreements.** Previously, rural hospitals that began residency training programs on or after January 1, 2005 were able to establish affiliation agreements with hospitals that had existing residency programs. CMS now proposes to allow urban hospitals that create a new residency program to establish an affiliation agreement with another hospital so long as the agreement results in a positive adjustment to the hospital's resident FTE cap. This would prevent hospitals from creating new residency programs and then moving most or all of its residents over to an existing program. **The AHA supports the expansion of the hospitals that may enter into affiliation agreements.**

## IME Adjustment

No IME FTE count was calculated for those hospitals that were exempt from the inpatient PPS for cost-reporting periods ending on or before December 31, 1996. Thus, for inpatient PPS exempt hospitals that wish to covert to the inpatient PPS, CMS proposes to establish the IME FTE count on the GME FTE count based on the cost reports ending on or before December 31, 1996.

With regard to the period used for determining the cap amount (whether for a converting hospital or a converting unit), it is inappropriate to use nearly 10-year-old data for the establishment of an IME resident cap. We acknowledge that an audit by the fiscal intermediaries was performed for *direct* GME purposes and the data may be available at this late date to establish an IME resident cap using that data. That said, teaching hospitals have made educational and program decisions regarding expansions of residency training rotations within those hospitals (and units) since 1996 with the understanding that the teaching hospital will not be penalized for Medicare reimbursement purposes apart from a penalty associated with possibly exceeding the hospital's direct GME cap. For CMS to state now, nine years later, that converting entities will revert all the way back to the 1996 resident cap levels for IME purposes and possibly be immediately above their IME resident cap when these program decisions and commitments have already been made to residents is inappropriate.

There is ample precedent for CMS to use a more updated data source for establishing the IME cap for hospitals and units converting to the inpatient PPS without an accompanying legislative change. The inpatient psychiatric PPS developed by CMS established an IME cap for those facilities *and units* based on the most recent cost reporting period prior to November 15, 2004, and the inpatient rehabilitation PPS proposed rule recently published by CMS contemplates the last cost reporting period ending on or before November 15, 2003 for the establishment of an IME cap for those facilities and units. **The AHA recommends that CMS use either or both of these cost reporting periods for the establishment of the IME cap in situations where a hospital or unit is converting and will be newly subject to the inpatient PPS.**

## Specialty Hospitals

In the inpatient PPS notice, CMS reported that some limited-service hospitals (CMS refers to them as "specialty hospitals") might not meet the Medicare statutory definition of a hospital and therefore were not eligible for Medicare certification as a hospital. If physician-owned limited-service providers are not hospitals, then their physician-owners also are not eligible for the protection of the "whole hospital" exception under the federal physician self-referral law. This

conclusion appears to be drawn from CMS' review of applications for grandfathering under Sec. 507 of the MMA that imposed an 18-month moratorium on physician self-referrals to certain new limited-service hospitals. It undoubtedly also was drawn from the fact that both the MedPAC and CMS congressionally-mandated studies of physician-owned limited-service hospitals have been unable to include surgical and orthopedic hospitals in many of their analyses because these facilities had so few inpatient admissions. It appeared that many of these hospitals – especially surgical and orthopedic hospitals – were focused predominantly on outpatient surgery.

Subsequently, in testimony before Congress, CMS announced its plan to revisit the procedures by which applicant hospitals are examined to ensure compliance with relevant federal standards, as well as an examination of how limited-service hospitals should be treated under EMTALA. Further, CMS indicated that its fiscal intermediaries had been instructed to refrain from processing Medicare participation applications from limited-service hospitals until a comprehensive review of its hospital provider enrollment process was completed. This process is expected to take at least six months. On June 9, the day after the congressional moratorium expired, CMS issued a fact sheet outlining next steps. The fact sheet provided additional details on CMS' plans to solicit input on these issues. It also indicated that the instructions to fiscal intermediaries included suspension of authorization for initial surveys by state survey agencies during the review period. Finally, it indicated that the suspension would not apply to limited-service hospitals that had submitted an enrollment application or requested an advisory opinion regarding grandfathering under the physician self-referral moratorium prior to June 9, 2005.

**The AHA commends CMS for recognizing this issue, undertaking this review, and suspending limited-service hospital enrollment applications in the interim**. We would like to take this opportunity to comment on the issues raised by this action, not only in the inpatient PPS notice but also in CMS' subsequent notices. We will address:

- Application of (COPs) statutory definition of a hospital and the Medicare hospital conditions of participation to limited-service hospitals.
- Treatment of physician-owned limited-service hospitals during the review process.

**Application of the Definition of a Hospital and Medicare COPs.** We appreciate the complexity of CMS' task in applying the statutory definition of a hospital, especially the requirement that the entity be primarily engaged in providing services to inpatients. While it has been amended across time, it is still a 40 year-old definition that is not necessarily reflective of current medical care and technology. Of necessity, we believe CMS will need to exercise some flexibility. Also, the Medicare hospital COPs have been undergoing a process of updating and revision for several years that is not yet completed.

First and foremost, **the AHA recommends that CMS focus on what the public expects of any entity labeled a "hospital" whether it is a full-service or limited-service hospital.** All Medicare-certified hospitals should have to meet all relevant Medicare COPs. With respect to limited-service hospitals, we believe most of the **core requirements that CMS should stress are already in place but require more rigorous enforcement. The area that we believe needs to be addressed with new requirements is the handling of patients with complications**

**and the transfer of patients from limited-service hospitals to full-service community hospitals. Specifically, we recommend the following core requirements for limited-service hospitals:**

- **An adequately staffed inpatient capacity**, including a fully-functioning quality monitoring and improvement system. The Medicare COPs already require this.

- **The ability to deal with complications that may arise during or after a surgical procedure in a way that protects the patient's well-being**. That means internal teams capable of handling complications typical to the procedures normally performed in that hospital and, when transfers are needed to access other specialties or services at another hospital, EMTALA-like provisions should apply with respect to how the transfer is executed and communicated with the receiving hospital. (Other comments related to the application of EMTALA to limited-service hospitals will be addressed separately in comments to the EMTALA Technical Advisory Group.) In the case of limited-service hospitals, we also believe that **specialty hospitals should disclose to their patients upfront that if complications occur outside their limited capability, patients would be transferred to another hospital**.

- **The ability to appropriately respond to emergencies.** Current hospital COPs related to emergencies should be strictly enforced. This does not require that every hospital have an emergency department. Under the COPs, hospitals that do not offer emergency services are required nonetheless to ensure that they have the ability to appraise emergencies, initially treat, and refer when appropriate. This requires more than simply dialing 911 and waiting for an ambulance to arrive. Hospitals that do offer emergency services (whether by choice or by state requirement) should be required to fully meet the provisions of 42 CFR 482.55. As identified by MedPAC's March 2005 report, some physician-owned limited-service hospitals have what they call an emergency department in order to meet state hospital licensure requirements but, given MedPAC's description of what they found, some of those hospitals cannot possibly be in compliance with the provisions of Sec. 482.55. If a hospital holds itself out as having emergency services, that proffer must be real or the public's health and safety will be endangered.

- **A fully-functioning discharge planning process and relationships with post-acute providers in the community**. The AHA believes this current Medicare requirement is especially important for Medicare beneficiaries given CMS' finding that physician-owned limited-service hospitals have shorter lengths of stay and higher readmission rates. While discharge planning is required of all hospitals, CMS' findings suggest that some physician-owned limited-service hospitals may have inadequate discharge planning processes and, as a result, Medicare patients are being sent home too quickly or without adequate post-discharge support.

We would urge caution, however, with respect to how CMS judges whether a hospital is primarily engaged in providing services to inpatients. The delivery of health care has changed significantly in the 40 years since Medicare was enacted. Many hospitals are now health care systems that provide a wide range of inpatient and outpatient care. **The AHA recommends that**

**CMS look at a hospital's operation comprehensively to ascertain whether the facility is *significantly* (or *seriously* if you will) engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care.** There is a significant difference between a hospital with 278 hospital beds that has 14,400 inpatient discharges and 94,500 hospital inpatient days a year that provides almost 80 percent of its care to outpatients because of the scope of services offered, and a limited-service hospital with eight beds, only 537 inpatient discharges and 1,200 hospital inpatient days a year that also provides almost 80 percent of its care to outpatients. The fact that most physician-owned surgical and orthopedic hospitals' performance often could not be measured under the MedPAC and CMS studies due to insufficient numbers of inpatient discharges is telling.

CMS also should consider whether the inpatient component of the hospital, even if small, represents a vital health care resource as in the case of a small rural hospital or a highly specialized center of excellence.

**Treatment of Physician-Owned Limited-Service Hospitals During the Review Process.** The AHA was surprised to see in the June 9 notice that CMS would not be applying the suspension of the enrollment process for limited-service hospitals across the board. Despite the fact that many of these hospitals have had their applications pending during review of whether they were eligible for grandfathering under the physician self-referral moratorium, it is difficult to understand how CMS plans to act on those applications when it has not yet completed its review of standards and the hospital provider enrollment process. Consequently, **the AHA recommends that CMS apply the suspension of processing enrollment applications for all limited-service hospitals until its review is completed and appropriate revisions adopted.**

As indicated in our May 24 letter to CMS, **the AHA also recommends that the agency use its authority granted under 1861(e)(9) and 1877(d)(3) of the Social Security Act to extend the application of the physician self-referral moratorium's conditions for grandfathering of existing physician-owned limited-service hospitals until CMS completes its review and Congress acts on pending legislation regarding self-referral to physician-owned limited-service hospitals.** In addition to overall patient health and safety concerns, there are several important reasons for CMS to administratively extend the application of the growth limitations under the moratorium:

- It would maintain the status quo while CMS conducts its review and Congress is deciding what action it will take.

- It would avoid any significant growth in volume prior to implementation of expected payment changes.

- It would avoid unnecessary administrative complications that could arise if currently grandfathered physician-owned limited-service hospitals take significant steps to grow or change when there is a possibility that congressional action will reach back to the June 8 sunset of the original moratorium.

## LTCH DRG Relative Weights

The proposed rule includes the recalibrated weights for the long-term care hospital (LTCH) DRGs, which CMS estimates would reduce Medicare payments to LTCHs by $135 million in FY 2006. When calculating the proposed weights, CMS used a new methodology that removed statistical outliers and cases with a length of stay of up to seven days from the reweighting calculation. In the proposed rule, CMS said that outlier cases were removed from the calculation because they "may represent aberrations in the data that distort the measure of average resource use" and that short-stay cases were removed since they "do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH." The AHA is concerned that the proposed methodology inappropriately removes too many LTCH patients from the reweighting calculation. By narrowing the pool of cases used to determine the relative weights for LTCH DRGs, the agency would erode a fundamental feature of the prospective payment system – the principle of averaging.

Further, the AHA is concerned that the LTCH DRG reweighting methodology would not achieve an adequate level of accuracy and that two types of cases may be under-represented in the data. A Lewin Group analysis of the December 2004 MedPAR file, in combination with data validation by a sample of LTCH providers, indicates that interrupted-stay patients and patients who transition from Medicare to Medicaid status during an LTCH stay are under-counted in the LTCH DRG reweighting. **The AHA urges CMS to re-examine these categories of cases to ensure that charges for these and all cases are fully accounted for in the proposed weights to avoid any unwarranted lowering or redistribution of the weights.**

The reweighting of the DRGs also raises concerns since the new weights are not being introduced in a budget neutral manner, even though the statutorily-required budget-neutral transition of the LTCH PPS is still underway. While we recognize that most LTCHs have already opted to transition to the PPS rather than be paid under a blended PPS/cost-based rate, it should not be overlooked that Congress established a five-year transition for the implementation of the LTCH PPS in order to avoid instability and disruption. Yet the proposed FY 2006 reweighting of the LTCH DRGs would generate a substantial reduction in Medicare payments to LTCHs.

In order to mitigate the substantial impact of this provision – estimated by CMS to be a 4.7 percent reduction and by The Lewin Group to be a 6.7 percent reduction – CMS should limit large swings in the LTCH DRG weights as it did in FY 2003 for the outpatient PPS. In that situation, CMS adopted a dampening policy that applied when an APC's weight decreased by more than 15 percent. In those cases, any decrease greater than 15 percent was reduced by half. **The AHA strongly encourages CMS to implement a similar transition or dampening method as part of the recalibration of the LTCH DRG weights.**

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AAMC

**VIA HAND DELIVERY**

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June 24, 2005

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Attention: **CMS-1500--P**

Dear Administrator McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates."* 70 Fed. Reg. 23306 (May 4, 2005). The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our letter comments on the proposed changes to the regulations for Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. We also comment on a number of other proposals that have particular importance to teaching hospitals. In particular, we urge the Agency not to expand the post-acute care transfer policy, and to reduce the proposed outlier threshold to $24,050. In addition, we believe it is premature to change the labor-related share.

## I. IME RESIDENT CAPS FOR FORMERLY INPATIENT PPS-EXCLUDED HOSPITALS AND UNITS

PPS-excluded rehabilitation and psychiatric hospitals and distinct-part units of acute care hospitals do not receive IME payments under the inpatient acute care prospective payment system (PPS) because their payments are determined by different systems.[1]

[1] Until recently, these units and hospitals were paid on a cost-based system. However, they currently are paid based on either the inpatient psychiatric facility PPS or inpatient rehabilitation facility PPS. The psychiatric PPS has its own IME adjustment. CMS has recently proposed to include an IME adjustment as part of the IRF PPS (70 Fed. Reg. 30188 (May 25, 2005)).

Consequently, they do not have inpatient PPS IME resident caps. However, these hospitals and units receive DGME payments and thus have DGME resident caps.

The proposed rule appropriately recognizes that there may be times when a PPS-excluded teaching hospital may have its Medicare status changed such that it would be subject to the inpatient PPS. While not explicitly mentioning PPS-excluded units, the situation is also applicable to them. In both of these situations, the hospitals and units that are training residents are eligible to receive IME payments under the inpatient PPS system. However, because they were not subject to the acute inpatient PPS in 1996--the time frame for determining the IME resident caps--their IME resident counts are not associated with the caps.

We acknowledge CMS' position that, as is true for other inpatient PPS teaching hospitals, PPS-excluded teaching hospitals that become subject to the acute inpatient PPS must also be subject to an IME resident cap.

While the proposed rule does not explicitly mention them, we presume CMS' position also applies to PPS-excluded units. Such a presumption is reasonable given that the situation for PPS-excluded units is the same as PPS-excluded hospitals. For example, if a teaching hospital had residents training in a rehabilitation unit in 1996 that was not PPS-excluded, those residents would be included in its IME cap. If the rehabilitation unit was PPS-excluded, the hospital was not permitted to include the resident counts in its 1996 IME cap calculation. If the PPS-excluded rehabilitation unit subsequently changes its status such that it now receives inpatient PPS payments (including IME payments), it is reasonable that the unit's resident counts should also be subject to an IME cap. Accordingly, the hospital's IME cap should be adjusted to reflect the additional resident counts. [2]

CMS proposes that for PPS-excluded hospitals that subsequently become subject to the inpatient PPS, the IME cap that would be established for them would equal the resident count that was used to establish their DGME cap--1996 for most teaching hospitals. At the outset, we believe that, at a minimum, the methodology that is ultimately decided upon by CMS must apply to PPS-excluded units as well.

We also believe that 1996 is too far back in time for establishing the IME caps for these facilities. While we recognize the CMS traditionally chooses a historical time period for decisions such as this[3], it is important to remember that 1996 was the year chosen for the

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[2] The only other alternatives would be to a) not subject resident counts in these units to a cap, which seems counter to current law which imposes an IME cap on hospitals subject to the acute inpatient PPS, or b) not adjust the hospital's resident cap when a PPS-excluded unit changes status, which could result in effectively denying hospitals IME payments associated with resident counts in those units. Not only would the result under b) be nonsensical, it would be contrary to statutory intent and current regulations that provide for IME payments under the inpatient PPS.

[3] A past time frame is usually used so that hospitals will not have an opportunity to change their behavior patterns in response to the legislation; for example, to increase resident counts before the imposition of a

DGME caps because it was the most recent year prior to the passage of the Balanced Budget Act of 1997 (BBA), which established the caps. That year was chosen so that the cap numbers would reflect as closely as possible hospitals' situations as of the time the BBA was enacted. To impose a 1996 time frame on a policy that is being implemented in 2006 is counter to this philosophy. Moreover, teaching hospitals have made educational and programmatic decisions regarding expansions of residency training rotations within those hospitals and units since 1996 with the understanding that the hospital is making those decisions absent a financial penalty apart from that associated with Medicare direct GME reimbursement by exceeding the hospital's direct GME cap. To use a cap based on hospitals' situations in 1996--10 years ago, is unfair and wrong.

We urge CMS to make cap determinations based on more current data. The psychiatric and rehabilitation facility prospective payment systems provide cap methodologies that use more recent cost report periods.[4] Not only are these easily adaptable to the inpatient system, they also would ensure resident cap consistency when an excluded facility converts to an acute inpatient status. Under the inpatient psychiatric facility (IPF) PPS, an IME cap is established based on the number of residents training in the IPF as reported by the hospital or unit in its most recently filed cost report before November 15, 2004 (See IPF PPS Final Rule, 69 Fed. Reg. at 66955). If a psychiatric PPS-excluded hospital or unit subsequently becomes subject to the inpatient acute care PPS, using this same cap would maintain consistency across payment systems.

Under the 2006 inpatient rehabilitation facility (IRF) proposed rule, a resident cap would be established based on the number of residents reported by the IRF on its most recent cost reporting period on or before November 15, 2003 (70 Fed. Reg. at 30243). We believe consistency dictates that for those IRFs which lose or change their status and become subject to the acute care inpatient PPS, the IRF PPS IME cap should be used.

## II. DGME INITIAL RESIDENCY PERIOD (IRP) DETERMINATIONS FOR SPECIALTIES REQUIRING A GENERAL CLINICAL TRAINING YEAR

Initial residency periods (IRPs) are used to determine Medicare DGME payments. Residents are counted as 1.0 full time equivalents (FTEs) during the number of years required to achieve first board eligibility, known as the initial residency period (IRP), though no resident can be counted as a 1.0 FTE for more than five years. For any training beyond the IRP, residents are counted as 0.5 FTEs.

CMS historically held the position that the IRP for residents in specialties that require a general clinical training year (for example, radiology, anesthesiology, and dermatology,) is determined based on the specialty of the first residency program they enter, rather than the second year program, which reflects their intended specialty of training. Thus, a

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resident cap.

[4] We are no opining as to the legality of CMS' decision to impose resident caps under either the IPF or IRF prospective payment systems.

resident who enrolls in a preliminary year internal medicine program is assigned the internal medicine IRP of three years, even if that is not the resident's ultimate specialty choice.

In last year's FY 2005 IPPS final rule, CMS stated that effective for portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident "simultaneously matched" for one year of training in a particular specialty residency program and for a subsequent period of training in a different specialty program, the resident's IRP will be determined based on the period of board eligibility associated with the second program.

The proposed rule broadens CMS' policy by allowing hospitals that can document that a resident matched to an advanced residency program beginning in the second year prior to the commencement of any training, the resident's IRP will be determined based on the advanced specialty, even if the resident had not matched for a clinical base year program.

We appreciate and support the proposal. However, we continue to believe that the IRP for residents whose first year of training is completed in a program that provides a general clinical year of training should be based on the specialty the resident enters in the second year of training, regardless of whether, or when, the resident matches to the advanced specialty program.

Not only would this be a much more straightforward--and administratively less burdensome--solution, it also would reflect Congress' statutory intent regarding initial residency periods, as reiterated by the Conference Committee agreement accompanying section 712 of the Medicare Modernization Act (P.L. 108-173):

> The conferees also clarify that under section 1886(h)(5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

## III. PROPOSALS AFFECTING BOTH DGME AND IME PAYMENTS

### A. NEW TEACHING HOSPITALS' PARTICIPATION IN MEDICARE GME AFFILIATED GROUPS

Under current regulations, existing teaching hospitals that meet specified criteria may enter into Medicare GME affiliation agreements by which they combine their respective resident caps and then redistribute them according to their agreement--with the proviso that the sum of the new caps cannot exceed the aggregate combined cap. Currently, 42 C.F.R. §413.79(e)(1)(iv) specifies that new teaching hospitals that are located in urban areas cannot be part of Medicare GME affiliated groups. New rural teaching hospitals may enter into these agreements but only if the rural hospital provides training for at least one-third of the FTE residents in all of the joint programs of the affiliated hospitals.

CMS states that its rationale for the new teaching hospital provision is to prevent "gaming" by current teaching hospitals that might encourage nonteaching hospitals to become teaching hospitals, receive a resident cap, and then enter into a GME affiliation agreement in which they would transfer many of their cap slots to the existing teaching hospital. A more flexible standard is provided for new rural teaching hospitals because rural hospitals may not have sufficient patient volume to support residency training programs.

The proposed rule would allow a new urban teaching hospital to enter into GME affiliation groups but only if there is a "positive adjustment" to its direct GME and/or IME cap; that is, the new teaching hospital's revised cap pursuant to the affiliated agreement must be higher than its base year cap.

While we favor this proposal, we continue to believe the overall policy is unnecessary. Hospitals do not decide to become teaching institutions and go through the rigors of the accreditation process without extensive thought and analysis. CMS has provided no evidence that so-called "gaming" has occurred. Even if such a concern existed, it could be addressed by limiting the affiliation group exclusion for new urban teaching hospitals to a specified period of time, for example, three years.

### B. RESIDENT CAPS FOR HOSPITALS CHANGING GEOGRAPHIC STATUS

Under the resident cap provisions, rural hospitals' resident caps equal 130 percent of their base year (generally 1996) resident counts and their resident caps are increased to reflect new residency programs. These provisions do not apply to urban teaching hospitals.

As a result of labor market definitional changes, some rural teaching hospitals are now considered urban. Under the proposed rule, these hospitals would retain their 130 percent cap determination, as well as any new program cap expansions that occurred while they were classified as rural. We support both of these proposals.

Also, urban hospitals that received cap increases for rural training track programs may retain those increases even if the rural "track" has been re-designated as urban due to new labor market definitions.

The situation is different for an urban hospital that had applied and been approved to be reclassified as rural under section 1886(d)(8)(E) (codified at 42 C.F.R. §412.103) and then returns to being urban. First, according to CMS, urban hospitals that reclassify to rural under this section may receive the rural cap adjustments (130 percent and new program expansions), but only for their IME cap. This is because under the statute the reclassification affects only payments made under section 1886(d) of the Medicare statute. While IME payments are authorized under this section, DGME payments are authorized under section 1886(h). Consequently, CMS states that only the IME cap is affected by the change to rural status. If the hospital subsequently rescinds its rural

reclassification status and returns to being urban, CMS proposes that the hospital would forfeit any IME cap adjustment that it received during its rural status.

According to the proposed rule, CMS believes it is appropriate to allow rural hospitals that become urban due to labor market definitional changes to retain permanently any upward cap adjustments that occurred while they were considered rural because the labor market changes were not within their control. This is in contrast to those urban hospitals that voluntarily chose to change their status to rural under section 1886(d)(8)(E) and then return to urban status. CMS is concerned that some hospitals would seek rural status for a short period only to receive the upward cap adjustment. While we question this concern, we believe that it is not applicable if a hospital retains its rural status for a significant period before changing back to an urban status. Thus, we recommend that urban teaching hospitals that reclassify to rural status for a significant period of time before returning to urban status (for example, three years) should be permitted to retain any upward cap adjustments that occurred during the period in which they were considered rural.

## IV. OTHER PROPOSALS OF PARTICULAR IMPORT TO TEACHING HOSPITALS

### A. POST-ACUTE CARE TRANSFER PAYMENT POLICY

Medicare patients who are sent from one acute care hospital to another are viewed as "transfers." The transferring hospital is paid a per diem rate based on the diagnosis-related group (DRG) payment and the number of days spent at the transferring hospital; the receiving hospital receives the full DRG payment.

In Federal fiscal year (FFY) 1999, in accordance with the BBA, CMS expanded its transfer policy such that hospitals that discharge patients associated with one of 10 specified DRGs to a post-acute care facility – such as rehabilitation hospitals and units, psychiatric hospitals and units, cancer, long-term care and children's hospitals, skilled nursing facilities, or are discharged home and receive home health services within three days after the date of discharge – would receive payments under the "post-acute care (PAC) transfer" policy. In subsequent years, CMS further expanded the post-acute care transfer policy, and as a result, a total of 30 DRGs were subject to the PAC transfer policy in FFY 2005.

CMS is proposing to expand--again--the post-acute care transfer policy, from 30 to 223 DRGs. DRGs that meet the following criteria would be subject to the PAC policy:

- The DRG has at least 2,000 discharges to post-acute care;
- At least 20 percent of cases in the DRG were discharged to post-acute care;
- Out of the cases discharged to post-acute care, at least 10 percent occur before the geometric mean length of stay for the DRG;
- The DRG has a geometric mean length of stay of at least 3 days; and

- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

According to CMS, this proposed expansion would result in $880 million less in Medicare program payments to hospitals, the equivalent of a 1.1 percent decrease in payments. Our analyses show a reduction of $894 million when the effects of IME, disproportionate share, capital and outlier payments are considered.

Simply put, CMS should not implement an expansion of the post-acute care transfer policy. Such a policy penalizes hospitals that ensure that Medicare patients receive care in the most appropriate setting. Moreover, it undercuts the fundamental principle of the PPS, which is that some cases will cost more than the DRG payment, while others will cost less, but on average, the overall payments should be adequate. It also is important to recognize that to the extent there still are cost reductions associated with discharging patients to post-acute care facilities (a debatable presumption given the current low average lengths of stay), such reductions will be reflected in lower DRG case weights during the DRG recalibration process.

We agree with comments by the American Hospital Association (AHA) that this proposal does not comport with the statutory directive that CMS focus on those DRGs that have a *high volume* of discharges to post-acute care and a *disproportionate use* of post-discharge services (emphasis added). (SSA section 1886(d)(4)(J)(ii)). Moreover, contrary to CMS' assertion that the PAC transfer policy levels the playing field for rural hospitals that do not have access to post acute care that is comparable to urban hospitals, AHA analyses show that rural patients have essentially the same access. Consequently, the proposed rule would harm all hospitals. We urge the Agency to rescind this proposal.

## B. OUTLIER PAYMENT THRESHOLD

If the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any disproportionate share (DSH), IME, or new technology add-on payments) plus a fixed-loss cost threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

The cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that will result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus $26,675, an increase of 3.4 percent over the FFY 2005 threshold of $25,800.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FFY 2005 will represent only 4.4 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 3.5 percent of total DRG payments in FFY 2004. Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in both of these years, contrary to the intent of the outlier payment policy.

We believe the FFY 2005 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. In conjunction with the American Hospital Association and Federation of American Hospitals, we conducted an analysis that incorporates both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be $24,050 for FFY 2006. We would be happy to discuss this methodology with CMS and provide further details.

## C. LABOR-RELATED SHARE

The proportion of the PPS standardized rate to which the wage index is applied is known as the "labor-related share." CMS defines labor-related share as "the national average proportion of operating costs that are related to, influenced by, or vary with local labor markets. We believe that the operating cost categories that are related to, influenced by, or vary with local labor markets are wages and salaries, fringe benefits, professional fees, contract labor, and labor intensive services" (70 Fed. Reg. at 23391).

CMS proposes to decrease the labor related share from 71.1 percent to 69.7 percent. Such a reduction would reduce payments for hospitals with wage indices above one, but would not increase payments for hospitals with wage indices below one since the labor share for these hospitals is legislatively set at 62 percent.

We believe the labor share should remain at 71.1 percent. In the FFY 2003 rulemaking process, CMS analyses supported increasing the labor share to 72.5 percent, but the Agency ultimately withdrew its proposal to implement the increase citing a need to conduct further analyses (67 Fed. Reg. at 50042).

We agree with the American Hospital Association that more analyses are needed before making a change to the labor share. The large drop in the "other labor-intensive services" category merits further attention. We also believe the suggestion by the Greater New York Hospital Association to re-designate professional liability insurance as a labor-related cost deserves serious consideration.

## D. SUBMISSION OF HOSPITAL QUALITY DATA

The Medicare Modernization Act requires that in order for hospitals to receive their full market basket update, they need to submit quality data on ten quality measures established by the Secretary. AAMC supports public reporting of hospital quality data and as a result most of the AAMC's Council of Teaching Hospitals and Health Systems

(COTH) participated in the Quality Initiative and all eligible COTH hospitals have submitted their data on the 10 starter measures for the update.

The proposed rule sets forth a process that changes the criteria for receiving the full market basket update by tying the update to not only the reporting of the quality data, but passing the validation criteria as well. We support the idea of submitting and displaying clinically valid data on the Hospital Compare website; however, the proposed validation process is new and needs further refinement before it can be tied to a hospital's payment.

We recognize all of the work that was done by CMS in the Quality Initiative to establish a framework to facilitate the proper submission of quality data. The early days of the Quality Initiative provided much information on how to modify processes in order to ensure an efficient operation at a time where there was minimal risk to the hospitals. If nothing else, we learned that anything new needs time to be vetted, tested and refined before it is ready for codification.

There already has been data to reinforce the fact that all of the problems have not been worked out of the proposed validation system. For example, the latest preview of quality data by hospitals showed that many hospitals failed their validation due to a data error by the Clinical Data Abstraction Center (CDAC). This is the same center that is used to calculate the validation results for payment. This process is obviously too new and needs further testing before any kind of payment system can be linked to it.

We also have concerns about several aspects of the proposed validation process. First, the number of charts that are pulled in order to calculate the percent match rate is five. It is questionable whether five charts will provide a statistically significant test of validity. It also is much easier for hospitals to fail validation or have a lower score due to a data mismatch error or missing data with such a small sample size. We recommend that the sample size be increased.

Secondly, there were many issues with the initial submission of data on the 10 starter measures due to a misalignment between CMS and JCAHO. The interim fixes that were put in place were still causing errors and required manual review for those data elements. A very tedious process was undertaken to make sure that all CMS and JCAHO measures were in complete alignment effective January 1, 2005. Due to the known data problems with the measure misalignment, this is further evidence that validation should not be used on third and fourth quarter data and certainly should not be used for purposes of calculating the payment update. Therefore, we recommend that the first quarter FFY 2005 should be the first quarter in which the validation process is used for calculating full payment update that would occur in FFY 2007.

## E. MEDICARE PAYMENTS FOR NEW TECHNOLOGIES

Pursuant to the Benefits Improvement and Protection Act of 2000 (BIPA), in a September 7, 2001 final rule (66 Fed. Reg. 46902), CMS established a methodology that would provide additional payments to hospitals for new technologies that they use that are not

yet reflected in the DRG payment system. In order to qualify for the additional payments the new service must meet three criteria under the DRG system:

- The medical service or technology is considered "new" until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration – usually 2 to 3 years beginning with FDA approval,
- It must be inadequately paid under the DRG system. The adequacy of payment is established based on a threshold for each DRG (a list of qualifying thresholds by DRG can be found in Table 10 of the Addendum), and
- It must represent an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

The additional payment is based on the hospital's cost for the new medical service or technology. Medicare pays the lesser of a) 50 percent of the difference between the cost of the case with the new technology and the DRG payment, or b) 50 percent of the cost of the new technology.

Payments for new services and technology were initially subject to a budget-neutrality factor. However, the law was subsequently amended and add-on payments from FFY 2005 forward are no longer budget-neutral.

In FFY 2005, hospitals could receive additional payments for three new technologies.

For FFY 2006, CMS proposes add-on payments for only one technology-- Kinetra® Implantable Neurostimulator for Deep Brain Stimulation. This technology currently receives add-on payments; payments for the other two technologies were discontinued. Moreover, the Agency proposes to deny five of the eight applications it received. For two technologies, CMS will make a decision in the final rule, and for one device, CMS is not making a decision at this time.

We are dismayed about the number of applications that are being submitted for new technology payments. We also are concerned about CMS's decisions to not approve payments for new technologies for which applications have been submitted. Given the pace of innovation, it is somewhat incredulous that only one new technology merits additional payments. We urge CMS to conduct a study of this issue. It may be that the criteria should be modified to ensure that hospitals that utilize expensive new devices in the treatment of Medicare beneficiaries are adequately compensated for this cutting edge care.

## F. DRG RECLASSIFICATION FOR CASES INVOLVING EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

We appreciate CMS's analysis of the average charges associated with cases that involve Extracorporeal Membrane Oxygenation (ECMO) and support the proposal to assign these cases to DRG 541 (one of the tracheostomy DRGs). ECMO is a procedure to

create a closed hest, heart-lung bypass system by insertion of vascular catheters. It is used for severely ill patients; often these patients are children.

We appreciate CMS' recognition that often other insurers use Medicare DRG classifications and payment rates. Consequently, its efforts to ensure accurate DRG classifications for all cases, even those that are predominantly non-Medicare, help to ensure that hospitals are paid appropriately.

## V. CONCLUSION

Thank you for this opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health care community.

If you have questions concerning these comments, please feel free to call Robert Dickler, Senior Vice President, Health Care Affairs, or Karen Fisher, Senior Associate Vice President. These individuals may be reached at (202) 828-0490.

Sincerely,

Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC

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Providence Health System

TRANSFERS
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Q Data
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Hefter
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Smith
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Krushat
Treitel
Kelly
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Brooks
Fagan
Hue
Kenly
Miller

June 21, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**RE: Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates; Proposed Rule CMS-1500-P.**

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to thank you for the opportunity to provide our comments on the changes proposed by CMS to the Medicare Hospital Inpatient Prospective Payment System in its Notice of Proposed Rule Making on May 4, 2005. The Providence Health System is a faith-based, non-profit health system that operates 18 acute care hospitals with 3,712 beds in Washington State, Oregon, California and Alaska, along with freestanding long term care facilities, physician groups, home health agencies, assisted living, senior housing, PACE programs, and a health plan. In 2005 the Providence Health System served 181,853 acute care admissions. Over one-third of our system's gross revenue is charged to the Medicare program.

Providence is pleased to provide its comments and recommendations to CMS on the following issues contained in the proposed rule:

- Expansion of the postacute transfer rule to include 223 DRGs;
- Criteria for continued designation as a critical access hospital;
- Data requirements in order to receive the full market basket update;
- Outlier payment rates;
- Calculation of the wage indices;
- Revisions to the complications/comorbidities list; and
- DRG reclassifications

## "Postacute Care Transfers"

CMS is proposing substantive and significant changes to the criteria that are used to determine whether a DRG is included in the postacute transfer policy. As proposed, the policy would be revised as follows:

1. The DRG has at least 2,000 postacute care transfer cases, a reduction from the threshold of 14,000 codified in 42 CFR §412.4(d)(ii);
2. At least 20 percent of the cases in the DRG are discharged to postacute care, up from the 10 percent requirement found in 42 CFR §412.4(d)(iii); and
3. The current requirement that a DRG must have experienced a seven percent decline in the geometric mean length of stay over the most recent five-year period in order to initially qualify under the postacute care transfer policy [42 CFR §412.4(d)(v)] has been deleted.

As the discussion and the regulatory impact analysis demonstrates, the effect of these changes on providers is significant. The number of DRGs subject to the policy is dramatically increased and the financial impact is profound: The number of affected DRGs is increased from 30 to 223 – a sevenfold expansion – and the average provider loses 1.1% in payments which amounts to one-third of the total market basket increase. **Providence strongly believes that the basis for this policy change is not appropriate at this time.** The following three reasons underlie this conclusion:

1. The proposed expansion of the postacute care transfer policy rests upon an inadequate foundation given the current DRG system's lack of sensitivity to severity-of-illness measures;
2. The proposal to eliminate 42 CFR §412.4(d)(v) is inconsistent with the legislative history of Section 1886(d)(5)(J) of the Social Security Act and past discussions concerning 42 CFR §412.4; and
3. The proposal has the practical effect of assuming that an "early discharge" is done simply for economic reasons and does not recognize the very real distinctions between acute and postacute care.

***Expansion Builds Upon an Inadequate Foundation***

Elsewhere in this proposed rule (70 FR 23332) CMS notes that the current GROUPER and Complications and Comorbidities List does not adequately explain the variation in resource utilization and that there is a need to improve the DRG system to better recognize severity of illness. This perspective is consistent with MEDPAC's recommendation that the DRG definitions need to be modified to account more completely for severity differences among patients. As noted in the comments that follow, Providence supports CMS efforts to engage in further planning and design work to provide needed enhancements to the patient classification system and accompanying payment methodology. While Providence has many misgivings about the entire postacute transfer policy, we believe it is unwise to dramatically expand its reach at this time since it relies upon a system that lacks so many critical variables that could better explain patient severity and the need for subsequent postacute care. However, in the absence of this more refined approach one should not erroneously assume that a patient was discharged to postacute care as a substitute for acute care services, the premise that appears to be the major rationale for the entire postacute care transfer policy. If CMS were to proceed with its proposed expansion, the change in criteria would further compound these problems. Under the proposed

regulatory framework, a DRG could have as few as 40 postacute discharges *nationally* before the geometric mean length of stay and be included in the postacute care transfer policy[1].

***Terms of the Expansion are Inconsistent with Past History***

Furthermore, Providence believes that it is inconsistent with the legislative history of Section 1886(d)(5)(J) of the Social Security Act and the past regulatory text accompanying the development of 42 CFR §412.4 to eliminate use of the criterion at 42 CFR §412.4(d)(v) requiring a DRG to have experienced a seven percent decline in the geometric mean length of stay over the most recent five-year period in order to be initially under the postacute care transfer policy. While we certainly do not dispute the authority of the agency to expand the number of DRGs subject to the postacute care transfer policy, the conferees explicitly noted their position in their report accompanying Section 4408 of the Balanced Budget Act by stating,

> The Conferees believe that Medicare's payment system should continue to provide hospitals with strong incentives to treat patients in the most effective and efficient manner, while at the same time, adjust PPS payments in a manner that accounts for ***reduced hospital lengths of stay*** because of a discharge to another setting. (Emphasis mine)

Furthermore, the regulatory discussion that accompanied the development of the text cited at 42 CFR §412.4 and much of the initial HER analysis affirmed this perspective.

Additionally, the Secretary's discretionary authority to add DRGs to the initial ten conditions mandated by the statute was directed to those categories of patients with a high volume of discharges to postacute care and a disproportionate use of postacute care services (Section 1886(d)(J)(ii) of the Social Security Act). While Providence has had longstanding concerns with expansion of this policy, the criteria found at 42 CFR §412.4(d)(1)(ii) requiring a DRG had to have at least 14,000 postacute transfer cases more accurately reflects conditions with a high volume of postacute care than the reduced threshold of 2,000 cases. The increase (from ten to twenty percent) in the percentage of cases discharged before the geometric mean length of stay does not ameliorate these issues. Indeed, the practical impact of the revised criteria suggests that the proposed policy does not adequately make the distinctions that Congress intended to accompany any policy expansion by CMS. While Providence cannot argue with the quantitative outcomes of the more recent analysis conducted by CMS it appears to lack an adequate statutory basis and is certainly deserving of more discussion.

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[1] 70 FR 23416: 2,000 cases * 20% cases transferred to postacute care * 10% of such transfers before the geometric mean length of stay.

***Expansion does not Adequately Recognize the Differences in Postacute Care Use***

It has been suggested by some that the use of postacute care by Medicare beneficiaries discharged from hospital settings can largely be explained as a function of the strong incentive for hospitals to transfer patients early in their stay in order to minimize costs while still receiving the full DRG payment. While there can be no dispute that hospitals are under tremendous pressure to manage their costs of serving Medicare beneficiaries, as an organization with a core value of stewardship, physicians practicing at Providence hospitals have responsibly evaluated when a patient no longer needs acute care services. When that point in a patient's treatment regimen is reached the physician appropriately initiates a discharge order for the patient. We find nothing in the above description that is contrary to the Medicare statute, the conditions of participation for hospitals, or a conflict with the best interests of the patients. There is clear empirical evidence that patients who utilize postacute care settings do so for other than economic reasons. Research results published by Andrew Shatto in a recent issue of Health Care Financing Reviewing Review[2] documented that beneficiaries who use postacute care have more difficulty in performing activities of daily living when compared to those patients who do not utilize postacute care. Additionally, they are more likely to be widowed or in the case of patients who utilize skilled nursing facility services, they are more likely to live alone. Additional research involving the use of postacute services by patients following acute myocardial infarction (AMI) documented the fact that those utilizing postacute services were generally older, were more severely ill at admission, experienced more health-related events in the hospitals, and were less mobile at discharge.[3]

These research results are illustrative of the well-documented fact that postacute care is highly correlated with an individual's inability to perform the normal activities of daily living and the absence of an informal caregiver. The AMI study aptly concludes that the availability of support at home for patients from family members, such as a spouse or children, has been shown to predict postacute service use.[4] The proposed expansion of the postacute transfer policy does not take these variables into account and may indeed penalize a hospital for issues that are clearly unrelated to the supposed behavioral incentives of the discharging hospital.

***Conclusion***

In 2004 – in addition to its hospital-based services - the Providence Health System provided 504,354 days of nursing home care and supplied 895,312 home health visits and hospice days of care. In offering such a diverse collection of services it has always been our philosophy that all patients – including Medicare beneficiaries – should expect to

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[2] Shatto, Andrew, "Comparing Medicare Beneficiaries by Type of Post-Acute Care Received: 1999," Health Care Financing Review, Vol. 24, No. 2, pp. 140-142.

[3] Bronskill, Susan et al, "Post-Acute Service Use Following Acute Myocardial Infarction in the Elderly," Health Care Financing Review, Vol. 24, No. 2, pp. 81.

[4] Kane et al, cited in Bronskill, op. Cit., pp. 88

receive the right care, from the right provider, at the right time. This has been our approach to developing a continuum of care either directly or in partnership with others that we believe best meets the needs of those we serve. Payment systems can either encourage or frustrate this outcome: For the reasons discussed above, Providence believes that an expansion of the postacute care transfer policy is both unwise at this time and not justified.

## "Critical Access Hospitals"

Prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Congress had established three location-related criteria for designation as a Critical Access Hospital. Section 1820(c)(2)(B) of the Social Security Act stated that a State may designate a facility as a critical access hospital if the facility -

- 1820(c)(2)(B)(i) is a hospital that is located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D)) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E), and that
    - 1820(c)(2)(B)(i)(I) is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital, or another facility described in this subsection; or
    - 1820(c)(2)(B)(i)(II) is certified by the State as being a necessary provider of health care services to residents in the area.

Section 405(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 modified the criteria found at 1820(c)(2)(B)(i)(II) by eliminating - effective January 1, 2006 - a state's authority to certify a hospital seeking designation as a Critical Access Hospital as a "necessary provider of health care services to residents in the area." However, with respect to the treatment of existing hospitals that had previously received their status as a Critical Access Hospital under a state's exercise of its authority prior to January 1, 2006 the Congress was explicit: Section 1820(h)(3) of the Social Security Act states,

> In the case of a facility that was designated as a critical access hospital before January 1, 2006, and was certified by the State as being a necessary provider of health care services to residents in the area under subsection (c)(2)(B)(i)(II), as in effect before such date, ***the authority under such subsection with respect to any redesignation of such facility shall continue to apply notwithstanding the amendment made by section 405(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.*** (Emphasis mine)

Notwithstanding this provision, questions have arisen since enactment as to whether an existing Critical Access Hospital previously designated under the authority of section 1820(c)(2)(B)(i)(II) would lose its status as a Critical Access Hospital if it was rebuilt, became operational after January 1, 2006, and could not otherwise satisfy the criteria found at 1820(c)(2)(B)(i)(I) [the so-called "35 (or 15) mile rule"].

Before offering substantive comments on the agency's proposal, Providence first wants to stress the importance of CMS issuing clear guidance on this issue **now**. Great uncertainty has resulted from the lack of a policy and the confusion caused by conflicting decisions issued by various CMS regional offices. Absent CMS action, several providers will continue to face the Hobson 's choice of either choosing to proceed with construction and improve the accessibility and the quality of their services but with the possible loss of Critical Access Hospital status or do nothing. Faced with this choice, governing boards, management, and financing authorities are understandably unwilling to proceed in the face of such uncertainty and potential dire consequences. In short, CMS needs to act now. The logical question that follows is the direction that such a policy should take.

The agency has proposed differing treatment for these affected hospitals which would vary depending on whether they are classified as a "replacement," "relocation," or "cessation of business." Before commenting on this regulatory framework, it must be noted that these characterizations are nowhere to be found in the legislative history of Section 1820(c)(2)(B) of the Social Security Act. Furthermore, to place limits on the ability of an affected Critical Access Hospital to renew itself beyond whether the new location would continue to satisfy the criteria found in the state's rural health plan that previously served as the basis for the state's designation appears to conflict with a simple reading of Section 1820(h)(3) of the Social Security Act: That text clearly states that "...any redesignation of such facility shall continue to apply notwithstanding the amendment made by Section 405(h)1." However, assuming that this perspective will not convince the agency to revise and restrict its policy accordingly, Providence would offer the following comments on the proposed language found at 42 CFR 485.610(d) and as more fully described at 70 FR 23450 – 23453.

- **The date-related limitations contained in the definition of a "replacement" facility should be eliminated.** As proposed, a new facility will be considered a replacement only if the construction is undertaken within 250 yards of its current building or is sited on contiguous land that was owned by the CAH prior to December 8, 2003. We believe it is not reasonable to deny these affected Critical Access Hospitals the benefits of this designation and subject it to the cost and uncertainty of the relocation review process simply because it purchased the new site after the date of enactment. This language presents a number of fact-intensive problems that regional offices are not prepared to address such as what happens if an affected Critical Access Hospital assumed ownership on December 9, 2003? There is no public good that is achieved with the inclusion of any of the date-related limitations for either "replacements" or "relocations."
- **The proximity to the current location limit contained in the definition of a "replacement" facility should be eliminated.** As proposed, a new facility will be considered a replacement if the construction is undertaken within 250 yards of its current building or on contiguous land. Providence believes the criteria should be whether the affected Critical Access Hospital would continue to meet the criteria in the state's rural health plan that were in effect at the time the hospital was initially designated. However, to the extent that CMS elects to retain a

proximity-related requirement, Providence believes it should be within a five-mile radius of its current location.

- To the extent that a facility does not qualify as a "replacement" then it may be eligible for treatment as a "relocation." For the same reasons described above, **Providence would recommend that the date-related criteria be removed from the definition of a facility "relocation."** Simply put, if a facility just commenced its planning process but could not otherwise be treated as a replacement because of land issues then it could only retain its Critical Access Hospital status if it relocated so as to satisfy the 35 or 15-mile rule. However, this decision – while prudent from a reimbursement standpoint - could result in a changed service area and population base. This practical result appears to be at odds with the other criteria suggested for a Critical Access Hospital to qualify as a relocation facility. A similar outcome could occur if an application had to be submitted to the state by January 1, 2006 or that plans had to be underdevelopment by December 8, 2003.
- **The criteria used to evaluate a Critical Access Hospital seeking treatment as a relocation are overly broad and could have the unintended consequence of creating a mini-federal certificate of need process.** CMS lists several issues hat would be evaluated but does not provide a basis for determining how a decision would be reached. For example, CMS has proposed that an applicant demonstrate that the new facility will facilitate access to care and improve delivery of services to Medicare beneficiaries. Such a conclusion is almost inherent in any new construction project – especially when it is eliminating many of the old and outdated facilities. However, given the consequences of failing to establish one's status as a relocation, a fact-intensive document will be produced that will likely create a burden for both the provider and the regional offices. For these reasons we believe it is prudent just to create a standard that a state find that the hospital continues to meet the criteria at its new location that were in effect at the time the state designated the hospital as a necessary provider.

## "Hospital Quality Data"

CMS is proposing that hospitals only receive the full market basket increase mandated by statute if their data reported on the 10 CMS Quality Measures meets or exceeds a validation requirement of 80 percent reliability and has two consecutive quarters of publishable data. At first blush, Providence cannot argue with regulatory standards that require the submission of good data that is publicly available. We **currently** meet the proposed validation standards and have two quarters of publishable data. However, notwithstanding this performance Providence is not prepared to endorse this proposal until the implementation issues surrounding this proposal can be met – most likely in FY07.

First of all, we object to a standard that will be created using data that has already been submitted and for which the review process has passed. CMS needs to establish how the data will be used before it is submitted and subjected to a validation process. Again, call

out a direction well in advance of implementation so providers can react accordingly. To potentially lose one-eight of the value of the entire market basket increase on the basis of data that is no longer subject to our review is not appropriate.

Furthermore, as we surveyed our clinical quality leaders it is clear to us that there are a host of issues requiring attention before a proposal of this nature can proceed with confidence. There is a need for better communication between the abstractors and providers: As one of our leaders noted abstractors have not done a good job of communicating what are the appropriate standards. There has been a lot of confusion around any number of issues – i.e., the time entry that counts is the first recorded time in the chart – not the time the patient registered. For example, it was not clear that we could lose points on the validation score due to the optional test items on LDL-c not being answered. Nor are these issues entirely on the provider side: We have had issues where our patient demographic data was sent out on another hospital's reports. Providence is not trying to make policy based upon anecdotes but the system is so new to all parties that the implementation issues are still being uncovered and resolved. Once that work is completed CMS and providers should be prepared to embrace a validation process and mandate transparency. At this time (1) there is more work to be done and (2) use of data that is closed and not subject to correction is inappropriate.

## "CC List"

As noted elsewhere, Providence supports the efforts to continuously improve the ability of the patient classification system to better explain resource use. However, the ability of a system change to actually achieve this intended and worthy outcome is singularly dependent on the knowledge, training, and ability of the individual coding the claim to accurately capture the data. Some of the required resources are technical information system changes and other requirements are human. As Providence has been internally modeling the effect of APR-DRGs and other systems it has become apparent to us that there will need to be significant lead-time to implement these changes – even something that appears as simple as a revision to the CC list. Consequently, we would encourage CMS to set forth its intended implementation timeline more completely in its discussion of the final rule. A change as significant as a comprehensive revision of the CC list cannot be adequately implemented through a Notice of Proposed Rule-Making in May of 2006, a Final Rule published in late July of that year, and an effective date two months later.

## "DRG Reclassifications"

As noted in the preceding discussion, Providence supports efforts by CMS to further refine the DRG system and wants to commend the agency for its work described in the regulatory preamble with respect to the proposed refinement of the GROUPER and payment system for procedures involving drug-eluting stents – especially where more than one device or vessel was involved, revisions to the hip and knee groupings to account for procedures involving revisions, and encouraging the better coding in those cases where tPA was used to treat patients with ischemic strokes. As our discussion of

implementation issues associated with the proposed revisions to the CC list suggests, changing coding systems and educating those who input these data elements is a significant factor in our shared effort and responsibility to improve the accuracy of the classification and payment system.

## Other Continuing Comments

Finally, Providence would like to briefly reaffirm its positions taken with respect to some past issues that are consistent once again with the proposed policy direction set forth by CMS.

- **"CBSAs:"** Consistent with our comments filed last year, Providence continues to support the use of Core Based Statistical Areas as a basis for delineating urban and rural areas for purposes of applying the appropriate wage index.
- **"Occupational Mix Adjustment:"** Again, consistent with our comments filed last year, Providence continues to support the use of a ten percent weighting factor for the occupational mix adjustment. We believe CMS has shown an appropriate amount of caution and deference to the very real and profound redistributional effects among providers if greater weighting was applied. We believe that the correct balance has been achieved.
- **"Operating Payment Rates – Outliers"** Providence remains concerned with the difference between the amount that CMS projects will be spent in outlier payments from its proposed thresholds when compared with the actual funds withdrawn from the "standardized pool" and utilized for outlier payments. Last year CMS projected payments that would equal about 5.1 percent of total DRG payments but that amount now appears to actually be about 4.4 percent of total DRG payments. We would encourage some evaluation be conducted that would examine the practicality and effects of a correction similar to the update forecast error adjustment. We are not advocating for adoption of such a methodology at this time but rather some analysis.

Thank you again for the opportunity to comment on these proposed changes. If you have any questions, please contact Chuck Hawley, Vice President of Government Affairs, at (206) 464-4237 or via e-mail at chuck.hawley@providence.org.

Sincerely,

John Koster MD

John Koster, M.D.
President/CEO
Providence Health System

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June 23, 2005

JUN 23

DSH

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**VIA COURIER**

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Attn: CMS–1500–P

Re. DSH Adjustment Data

To Whom It May Concern:

We offer these comments on CMS's proposed implementation of Section 951 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). We encourage CMS to implement a unitary policy for furnishing MedPAR data to providers that will apply to all cost years. A single policy will be more equitable to providers and easier to administer than a policy in which different rules apply to different cost years. Specifically, for any cost year that is still subject to appeal or reopening, CMS should provide MedPAR data at no charge.

**Background**

The Medicare statute provides an additional payment to hospitals that serve a disproportionate share of low-income patients.[1] Whether a hospital qualifies as a disproportionate share hospital ("DSH"), and the amount of the DSH payment, are based upon a hospital's "disproportionate patient percentage" ("DPP").[2] The DPP is defined as the sum of two fractions.[3] The first fraction is commonly known as the Medicare fraction, and it is defined as:

> the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to

[1] 42 U.S.C. § 1395ww(d)(5)(F).
[2] Id. at § 1395ww(d)(5)(F)(v).
[3] Id. at § 1395ww(d)(5)(F)(vi)

> supplemental security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter . . . .[4]

The second fraction is commonly known as the Medicaid fraction. It is defined as:

> the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX [the Medicaid program] of this chapter, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.[5]

In 2000, CMS established its Medicare Provider Analysis and Review ("MedPAR") system.[6] One of the purposes of the MedPAR system is to calculate "Supplemental Security Income (SSI) ratios for hospitals that are paid under the PPS and serve a disproportionate share of low-income patients . . . ."[7] CMS's policy has been that MedPAR data is covered by the Privacy Act of 1974, and pursuant to the Privacy Act, CMS only releases data for "routine uses" that are compatible with the purposes for which the data were collected.[8] One of these purposes includes "an appeal properly pending before the Provider Reimbursement Review Board (PRRB) or before an intermediary on the issue of whether it is entitled to disproportionate share hospital payments."[9] CMS currently charges providers $1,200 for MedPAR data for cost reporting periods prior to federal fiscal year 1996 and $900 for all other cost reporting periods.[10]

In Section 951 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Section 951"), Congress required CMS to furnish hospitals with the data necessary to calculate the patient days contained in the DSH formula. That provision states:

> Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act,

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[4] Id. at § 1395ww(d)(5)(F)(vi)(I).
[5] Id. at § 1395ww(d)(5)(F)(vi)(II).
[6] 65 Fed. Reg. 50548 (Aug. 18, 2000).
[7] Id.
[8] Id.
[9] Id.
[10] *DSH Data Use Agreement, available at* http://www.cms.hhs.gov/privacyact/requests/cmsdshdua.pdf.

> 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.[11]

In the May 4, 2005 *Federal Register*, CMS proposed to implement Section 951 by changing its current policy for releasing MEDPAR data to providers.[12] First, CMS proposes to release MEDPAR data to providers regardless of whether they have DSH appeals pending before the PRRB. However, CMS plans to implement this policy only prospectively:

> Beginning with cost reporting periods that include December 8, 2004 (within one year of the date of enactment of Pub. L. 108-173 [Section 951]), we are proposing to furnish MedPAR . . . data for a hospital's patients eligible for both SSI and Medicare at the hospital's request, regardless of whether there is a properly pending appeal relating to DSH payments.[13]

Second, CMS proposes to cease charging providers for the data: "Because we interpret section 951 to require the Secretary to arrange to furnish these data, we do not believe that it will continue to be appropriate to charge hospitals to access the data."[14] It was unclear to us whether CMS intends to stop charging providers for all cost years or only for costs reporting periods that include December 8, 2004 and later cost years.

**CMS Should Implement One Policy for All Cost Years**

We strongly urge CMS to implement a consistent policy, applicable to all cost years, for the release of MedPAR data. First, CMS should amend its proposal to state that CMS will supply cost data for any cost year that is subject to appeal or reopening. Second, CMS should clarify that it will no longer charge hospitals to supply MedPAR data for any cost year.

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[11] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 951, 117 Stat. 2066, 2427 (2003).
[12] 70 Fed. Reg. 23434 (May 4, 2005).
[13] Id. at 23435.
[14] Id.

CMS Should Implement Section 951 For All Cost Years Subject to Appeal or Reopening

CMS proposes to implement Section 951 by dropping its requirement that a hospital have an appeal pending before the PRRB, but CMS plans to make this change beginning with cost reporting periods that include December 8, 2004, which is one year from the enactment of Section 951. Although CMS does not state its reason for implementing Section 951 only for cost years including December 8, 2004 and forward, CMS may be basing its policy on a narrow reading of Section 951. That statutory provision requires that CMS, "not later than 1 year after" enactment of Section 951, furnish hospitals with the data "used in computing the disproportionate patient percentage . . . for the *current* cost reporting year."[15]

We believe that Section 951 does not mandate that CMS only implement its policy for cost years that include December 8, 2004 and later years. Section 951 references three distinct time periods. First, CMS must implement Section 951 within one year. Second, CMS must provide the data "used" to calculate the DPP. The past-tense verb "used" can only refer to data that CMS has already compiled and employed for calculating a DPP. Because CMS calculates a hospital's DPP after the conclusion of a cost year, when data for that year becomes available, Section 951 seems to apply to cost years prior to the date of a request for MedPAR data.

However, Section 951 also states that CMS will furnish data "used" for "the current cost year," implying that Section 951 applies only to the cost year in effect at the time that the hospital requests its MedPAR data. This language is ambiguous, because a literal reading of Section 951 leads to an impossibility: CMS must provide data that has already been "used," but it may only provide that data during the "current cost reporting year," which necessarily falls prior to the data being compiled or "used."

CMS implicitly acknowledges this ambiguity by proposing a policy that does not limit providers to requesting data only for "the current cost reporting year." Instead, CMS plans to begin implementation for cost reporting periods that include December 8, 2004, but CMS makes no mention of when a provider must request data for that year.[16] As the CMS proposal is worded, a provider could presumably request its 2004 data during the 2004 cost year or at some time after the end of the cost year.

Because Section 951 is ambiguous, CMS has the discretion to implement it for all cost years. We urge CMS to amend its proposal and implement a policy that would allow providers to request data for any cost reporting period that is still subject to appeal or reopening. A consistent policy for the release of MedPAR data will be easier for CMS to implement and cause less confusion among the provider community. Implementing the policy proposed by CMS will create a dual system for the release of MedPAR data with different rules for the release of data

[15] MMA, § 951 (emphasis added).
[16] 70 Fed. Reg. 23435.

depending solely upon the cost year that is requested. This system will be administratively difficult for CMS to maintain and there is no valid reason for such a dual system. If MedPAR data may be released for cost reporting periods that include December 8, 2004, irrespective of whether a provider has appealed its DSH determination, the same data elements should also be released to the same provider for prior cost reporting periods.

CMS Should Not Charge a Fee for Any MedPAR Data

CMS should clarify that it will not charge a fee for any MedPAR data requests. We believe that the proposed rule is unclear on this point. On the one hand, CMS states that "we do not believe that it will continue to be appropriate to charge hospitals to access the data."[17] This implies that CMS will not charge hospitals to access MedPAR data for any cost year. On the other hand, CMS makes this statement in the paragraph immediately following its announcement that it will furnish data for cost reporting periods that include December 8, 2004 and after, regardless of whether a hospital has a pending DSH appeal. This could imply that CMS will also cease charging for the data only for cost reporting periods that include December 8, 2004 and after.

For the same reasons stated above, CMS should implement a consistent policy with respect to the fees charged for MedPAR data. We agree with CMS that Section 951 does not allow CMS to charge for the data. Creating a dual system for charging for MedPAR data will be difficult to administer, and it makes no sense to charge more for prior cost years than for cost years that include December 8, 2004 and later cost years. CMS has already compiled the data for these prior cost years. The cost to CMS to transmit it to providers therefore should be minimal and there should be no difference in costs to CMS for furnishing the data for different cost years.

**Conclusion**

For the foregoing reasons, we encourage CMS to implement a consistent policy for furnishing MedPAR data to providers in which CMS will provide data to any provider for a cost year that is subject to appeal or reopening at no charge.

Sincerely,

Barbara Straub Williams /RSC

Barbara Straub Williams

[17] 70 Fed. Reg. 23435.

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June 21, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
P.O. Box 8011
Baltimore, MD 21244-1850

**Subject File: CMS-1500-P**

Dear Dr. McClellan:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on that portion of the proposed rule published in the *Federal Register* on May 4, 2005, concerning proposed changes to the Hospital Inpatient Prospective Payment System (HIPPS) for fiscal year 2006. Specifically, ACCP is concerned that the proposed rule does not reinstate funding eligibility for 2nd year and specialized pharmacy residencies within the provisions for graduate medical education contained in 42 CFR Parts 412 and 413.

ACCP is a national professional and scientific society that represents almost 10,000 clinical pharmacist practitioners, researchers, and educators. Our members have been among the profession's leaders for almost three decades in providing professional services, consultation, cutting-edge clinical research, and educational leadership that improve the quality of medication use in the health care settings in which they practice.

More than 80 percent of ACCP's members have completed either a one-year pharmacy practice residency or a two (or greater)-year residency in a specialized area of pharmacy practice. Twenty-five percent of ACCP's members are board certified in one or more of the five pharmacy specialties recognized and certified by the Board of Pharmaceutical Specialties. Together with the American Society of Health-System Pharmacists (ASHP), which is the CMS-recognized accrediting body for hospital-based pharmacy residency training, ACCP has provided primary leadership within the pharmacy profession over the past quarter century in fostering the growth and development of residency training in pharmacy as an essential element of the educational preparation of pharmacists involved in the provision of contemporary pharmacy services.

Despite its initial proposal in 2003 to eliminate pass-through funding eligibility for all pharmacy residencies, CMS was ultimately persuaded by the comments from the pharmacy profession and others to amend its proposal and to continue funding eligibility for pharmacy practice ("first year") residencies. Additionally, at that time, the agency indicated that it would entertain the possibility of restoring funding eligibility for 2nd year/specialized pharmacy residencies at the point in time when it could be demonstrated that such training represented the "industry norm" for pharmacists practicing in those specialized areas.

The recent provision by ASHP of national survey data collected in 2004, which found that 82 percent of hospitals that employ clinical pharmacy specialists require specialized pharmacy residency training for those practitioners, demonstrates clearly that such training does indeed represent the "industry norm" for contemporary hospital pharmacy practice. Among these hospitals, nearly one-fifth will not fill a specialized clinical pharmacy position with someone who has not completed such a residency; the remainder will do so only if a specialty-residency trained candidate is not available.

In its previous ruling, CMS defined "industry norm" as meaning "that more than 50 percent of hospitals in a random, statistically valid sample require the completion of a particular training program before an individual may be employed in a specialty." ASHP submitted these survey results to CMS in July 2004 and again in March 2005.

Thus we believe that the standard that CMS imposed for restoring funding eligibility for 2nd year and specialized pharmacy residencies has now been clearly demonstrated to exist in the hospital practice setting. We would therefore strongly urge CMS to revise the proposed rule to reinstate Medicare pass-through funding eligibility for 2nd year and specialized pharmacy residencies beginning in fiscal year 2006.

As we noted in our letter of 2003, there are many substantive reasons that are far more important than the "industry norm" standard that CMS chose to impose in 2003 that should persuade CMS to allow, and even actively support, funding for both pharmacy practice and specialized pharmacy residencies. These include:

- The various recent reports from the **Institute of Medicine** outlining the critical importance of, among other things, (a) improved medication management for chronic diseases; (b) the necessity for enhanced interdisciplinary training and team-building in the delivery of high quality health care services; and (c) the critical need for closing the "quality chasm" in health care by improving the safety of, among many other elements, medication use. These are precisely the types of activities that pharmacy residency training prepares the contemporary pharmacist to perform. **In particular, it is during the residency training experience (for both disciplines) that essential and valuable professional relationships and trust are established between physicians and pharmacists that lead to more collaborative and effective management of patients' drug therapy.**

- The recommendation of the **Medicare Payment Advisory Commission** to Congress in June 2002 that the Secretary of HHS "...assess models for collaborative drug therapy management services" by clinical pharmacists working with physicians. Pharmacy residency training is an integral and essential component of the training of pharmacists to perform collaborative drug therapy management.

- **Congressional concern about the nation's shortage of pharmacists AND the pharmacy faculty needed to educate them has resulted in the introduction of the Pharmacy Education Aid Act in both the 107th and 108th Congress.** It is well recognized that the nation's need for qualified pharmacy faculty has never been greater as pharmacy schools seek to expand to meet the unprecedented demand for pharmacists detailed in the December 2000 report of the Bureau of Health Professions. For more than two decades, completion of residency training has been an essential criterion for employment of their clinical faculty by schools and colleges of pharmacy. Reduced support for residency training in pharmacy will only compound this faculty shortage.

- Completion of a pharmacy residency is among the key qualifying criteria for persons seeking to become certified by the **Board of Pharmaceutical Specialties** as a pharmacotherapy specialist. The growing cadre of pharmacotherapists in the U.S. will inevitably be at the forefront in assuring that drug therapy is effective, safe, and well-managed within our health care system.

- **The implementation and future success of the Medicare Part D prescription drug benefit in 2006 and beyond.** Pharmacy residency programs provide the essential experiences, skills development, and knowledge needed to manage and deliver the highest quality medication therapy management programs.

ACCP also noted in its 2003 comments that the likely rationale for eliminating funding eligibility for pharmacy residencies was to help control costs to Medicare associated with payments for graduate medical, nursing, and allied health professions education. Our estimates at that time suggested that total Medicare funding for pharmacy residency training in the U.S. was likely to be less than 0.1% of total GME funding. This amount (certainly less than $10 million/year) is practically inconsequential in the larger scheme of Medicare, and yet its loss for pharmacy is disproportionately devastating to the profession and to residency programs that provide the leadership to improve the quality of medication use in hospitals and health systems. Since funding eligibility for pharmacy practice residencies (which constitute the majority of pharmacy residency training in hospitals) was ultimately retained, the negative financial impact on Medicare of supporting 2nd year and specialized pharmacy residencies would now be, by any reasonable measure, truly microscopic within the total Medicare budget.

In summary, ACCP believes that the proposed rule concerning HIPPS payment rules for fiscal year 2006 related to GME funding should be revised to reinstate funding eligibility for 2nd year and specialized pharmacy residency training programs. We urge CMS to recognize the enormously positive benefit-to-cost ratio of this reinstatement, and look forward to a favorable decision in this regard.

Please do not hesitate to follow up with us if we can provide additional information or assistance on this important matter.

Sincerely,

Michael S. Maddux, Pharm.D., FCCP
Executive Director

C. Edwin Webb, Pharm.D., M.P.H.
Director, Government & Professional Affairs

cc: ACCP Board of Regents

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**Ref: CMS-1500-P — Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule.**

**Re: DSH Adjustment Data; Postacute Care Transfers; Outlier Payments**

Dear Dr. McClellan:

The National Association of Public Hospitals and Health Systems (NAPH) appreciates the opportunity to submit comments on the above-referenced proposed rule.[1] NAPH represents more than 100 metropolitan area safety net hospitals and health systems. Our members are significant providers of care to low-income and uninsured patients. For example, approximately 38 percent of the inpatient services provided by NAPH members is to Medicaid recipients, approximately 21 percent is provided to Medicare patients and another 23 percent is provided to uninsured patients. NAPH members also provide certain essential specialized services to their entire communities, such as emergency and trauma care, burn care, and neonatal intensive care. Our members are multifaceted health systems, often operating facilities at multiple sites and frequently serving as major training centers for medical residents and interns. Because of all of these characteristics, the proposed rule changes would significantly impact day-to-day operations of NAPH members.

With regard to the FY 2006 IPPS proposed rule, NAPH is particularly concerned that a number of the changes contemplated by the Centers for Medicare and Medicaid Services (CMS) will reduce Medicare payments to safety net hospitals at a time when they already provide care to Medicare patients at a significant loss. Recent analysis of NAPH member data from 2003 (the most recent year available) indicates that NAPH members lost approximately $1.1 billion treating Medicare patients. In total, approximately ninety percent of NAPH members reported losses on Medicare patients in 2003. Safety net hospitals like NAPH members cannot continue to sustain losses like these and maintain their multiple missions of patient care, specialized services to all, emergency preparedness, and educating our nation's physicians and other front-line providers. Changes like those contemplated in the proposed rule, particularly to the postacute care transfer policy and IPPS outlier payments will further jeopardize the situation of

[1] 70 Fed. Reg. 23305 (May 4, 2005), herein "Proposed Rule."

these providers. Our detailed comments are attached. In summary, NAPH urges CMS to consider the following recommendations:

- NAPH urges CMS to reconsider its proposed implementation of Section 951 of the Medicare Prescription Drug, Improvement and Modernization Act ("MMA") of 2003[2] and instead require that States amend their Medicaid State Plans and Medicaid provider agreements to require the accurate provision of patient Medicaid eligibility information to hospitals, including archived data. Furthermore, to ensure that hospitals have the necessary information to exercise their ability under federal regulation to request a Medicare cost report reopening, CMS should mandate that this information is provided within a reasonable period of time (e.g., 90 days). Finally as CMS has proposed with regard to Medicare patient information, CMS should ensure that Medicaid patient information is available to hospitals free of charge.

- NAPH strongly opposes CMS' proposal to expand the postacute care transfer policy to either an additional 223 DRGs or all DRGs. NAPH believes that by dramatically expanding a policy that already runs counter to the fundamental design of the prospective payment system, CMS risks severely disrupting or even destroying the very delicate balance of incentives which drive the IPPS. If CMS finalizes this proposal, then NAPH strongly urges returning any savings to the base DRG payment rates.

- NAPH opposes the proposed increase in the outlier threshold given that outlier payments over the last several years have been less than CMS' projections. The proposed approach unfairly penalizes hospitals with outlier cases, which are already reporting losses from treating these high cost patients and will only have to expend more resources to reach the higher threshold. Furthermore, we believe that CMS' charge-inflation methodology used to justify such an increase is flawed. We support the recommendation of the American Hospital Association (AHA) to utilize a dual cost-inflation and charge-inflation methodology to calculate the outlier threshold.[3] Such a methodology would result in an FY 2006 outlier threshold of $24,050. To account for the unspent outlier payments and attendant decreases in standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.

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[2] Pub. L. 108-173, December 8, 2003.

[3] See Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 24, 2005).

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Although we are not directly commenting on the following aspects of the proposed rule, NAPH joins AHA in requesting that CMS review and revise the methodology used to determine the projected FY 2006 market basket, urges CMS to leave the labor-related share at 71.1 percent for FY 2006 while continuing to investigate alternative methodologies for computing the labor-related share, and supports AHA's recommendations regarding physician owned specialty hospitals.[4] NAPH appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please contact Frederick Isasi at (202) 624-3969.

Sincerely,

Larry S. Gage
President

[4] *Id.*

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***COMMENTS ON PROPOSED CHANGES TO THE FY 2006 INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) RULE***

## I. DSH Adjustment Data

**NAPH opposes CMS' proposed implementation of Section 951 of the Medicare Prescription Drug, Improvement and Modernization Act ("MMA") of 2003[5] and urges CMS to impose more stringent requirements on States including mandating modifications to State plan amendments and Medicaid provider agreements to require accurate and timely provision of Medicaid eligibility information, including archived data, to hospitals free of charge for the purpose of calculating their Medicare Disproportionate Hospital Share (DSH) percentage.**

Under Section 951 of the MMA, HHS is mandated to "arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage..." This percentage includes both a "Medicare fraction" and "Medicaid fraction." To provide information required to calculate the Medicare fraction, CMS proposes to provide to hospitals MedPAR LDS data for patients eligible for both SSI and Medicare. Such information will be made available for the first time free of charge and regardless of whether or not a hospital has an appeal pending related to Medicare DSH payments. NAPH appreciates CMS' attempts to facilitate hospitals' receipt of MedPAR LDS data and believes that the mechanisms described in the preamble are adequate to meet the statutory mandate of MMA Section 951.

With regard to the information necessary to compute the Medicaid fraction, CMS proposes no change to the current practice of requiring hospitals to verify patient Medicaid eligibility with states. Specifically, CMS proposes to "continue to place the burden of furnishing the data adequate to prove eligibility for each Medicaid patient day claimed for DSH percentage calculation purposes on hospitals..."[6] CMS justifies this decision stating "in the vast majority of cases, there are established procedures for hospitals or their authorized representatives to obtain the information needed for hospitals to meet their obligation under § 412.106(b)(4)(iii) and to calculate their Medicaid fraction."

Although in some instances "established mechanism" may exist, they are far from adequate. NAPH believes that CMS' decision to continue to require hospitals to negotiate with States for Medicaid eligibility data does not fulfill CMS' statutory mandate to "*arrange to furnish*" the information necessary to calculate the Medicaid fraction and ignores the difficulty that many hospitals face in attempting to verify such data with their State Medicaid agencies.

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[5] Pub. L. 108-173, December 8, 2003.
[6] Proposed Rule, 70 Fed. Reg. 23436.

NAPH members report unnecessary delay in receiving Medicaid eligibility information from State Medicaid agencies and report that the data provided are often inaccurate. Such delays and inaccuracies can be particularly egregious when related to patients enrolled in Medicaid managed care plans and archived patient Medicaid eligibility data. In some instances, state Medicaid agencies outright refuse to provide the information or charge hospitals exorbitant fees for the information. Hospitals even report that their Medicare Fiscal Intermediaries (FIs) sometimes question the accuracy of the Medicaid eligibility information provided by the State and refuse to accept the information in relation to a Medicare cost report reopening.

We believe that it was Congress' intent to address these long standing problems in enacting Section 951 and requiring that CMS *"arrange to furnish"* Medicare DSH information. Such language clearly articulates Congress' intent that CMS implement *proactive* measures to ensure that necessary information is available to hospitals. Such measures should not include simply reiterating the current process for negotiating Medicaid eligibility information but should instead involve implementing new processes designed to ensure that necessary information is furnished to hospitals. Although requirements related to archived data may be beyond the scope of Section 951, NAPH believes that mandating accurate and timely reporting of such data free of charge is clearly within CMS' general authority in administrating the Medicaid program and is critical to hospitals' ability to exercise their ability under federal regulation to request timely Medicare cost report reopenings.[7]

**NAPH urges CMS to reconsider its proposed implementation of Section 951 of the MMA and require States to amend their Medicaid State Plans to require that accurate Medicaid patient eligibility information be provided to hospitals, including archived data. Furthermore, to ensure that hospitals have the necessary information to exercise their ability under federal regulation to request a Medicare cost report reopening, CMS should mandate that this information is provided within a reasonable period of time (e.g., 90 days). To ensure that hospitals have adequate legal recourse to insist on the provision of such information, CMS should also mandate that states reiterate their duty to provide such information in their Medicaid provider agreements with individual hospitals. Finally as CMS has proposed with regard to Medicare patient information, CMS should ensure that Medicaid patient information is available to hospitals free of charge.**

## II. Postacute Care Transfers

**NAPH strongly opposes CMS' proposal to expand the postacute care transfer policy to either an additional 223 DRGs or all DRGs. NAPH believes that by dramatically expanding a policy that already runs counter to the fundamental design of the prospective payment system, CMS risks severely disrupting or even destroying the very delicate**

[7] See e.g., 42 C.F.R. § 405.1801 *et. seq.*,.

**balance of incentives which drive the IPPS.** ***If CMS finalizes this proposal, then NAPH strongly urges returning any savings to the base DRG payment rates.***

In 1998, as required by the Balanced Budget Act (BBA) of 1997,[8] CMS created a new postacute care transfer policy that, in limited circumstances, treated the discharge of patients to a postacute care provider as a transfer for Medicare reimbursement purposes. In such instances the transferring hospital is reimbursed for the services rendered before discharge using a per diem rate. The BBA specified that this postacute care transfer policy applied to a limited set of 10 DRGs highly correlated to patients with shorter than average lengths of stay and who were subsequently discharged to post-acute care facilities. Thus, this policy is primarily aimed at reducing payments to providers that may be receiving a full DRG payment while prematurely discharging patients to postacute care treatment. The BBA also provided HHS with discretionary authority to further expand this policy for DRGs that may be associated with such inappropriate postacute care transfers.

In the FY 2004 IPPS rule, HHS chose to exercise its discretionary authority and expanded the postacute care transfer policy to include a total of 29 DRGs. In the proposed rule, CMS continues this trend and proposes to expand the postacute care transfer policy on a much broader scale to either an additional 223 DRGs or to all DRGs . The cost of expanding the policy to an additional 223 DRGs is estimated to result in reduction of payments to hospitals of $880 million in FY 2006 alone. CMS does not estimate the cost associated with expanding the policy to all DRGs.

NAPH has consistently opposed the expansion of this acute care policy, which we believe directly contradicts the fundamental design of the prospective payment system and creates a perverse incentive to keep patients longer so that hospitals may retain the full DRG payment. This policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place. The post-acute transfer provision disadvantages hospitals making sound clinical judgments about the best setting of care for patients – and this setting is more and more frequently outside of the hospital's four walls. In addition, facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients are disproportionately penalized. NAPH believes that by dramatically expanding a policy that already runs counter to the fundamental design of the prospective payment system, CMS risks severely disrupting or even destroying the very delicate balance of incentives which drive the IPPS.

The Medicare Payment Advisory Commission (MedPAC) estimates that broad application of the postacute care transfer policy may lead to some facilities receiving a reduction in IPPS payments of as much as 4 percent.[9] Given that the vast majority of NAPH members currently provide

[8] Pub. L. 105-33 ; See also Social Security Act § 1886(d)(5)(J).
[9] MedPAC Report to Congress: March 2003 at 46.

Medicare services at a loss and are operating with negative margins, such a significant decrease in IPPS payments could devastate our membership. We urge CMS not to finalize this ill-advised policy. However, in the event that CMS chooses to ignore our recommendation and finalizes this proposal, NAPH strongly urges that any savings be returned to the base DRG payment rates to moderate the impact of such a policy and ensure that IPPS payments are adequate.

**NAPH strongly opposes the proposed expansion of the postacute care transfer policy. If, however, CMS does finalize this ill-advised proposal, NAPH strongly urges returning any savings to the base DRG payment rates.**

**III. Outlier Payments**

**NAPH opposes the proposed increase in the outlier threshold, given that outlier payments over the last several years have been less than CMS projections. The proposed approach unfairly penalizes hospitals with outlier cases, which are already reporting losses from treating these high cost patients and will only have to expend more resources to reach the higher threshold.** ***Furthermore, we believe that CMS' charge-inflation methodology used to justify such an increase is flawed and support AHA's recommendation of utilizing a dual cost-inflation and charge-inflation methodology to calculate the outlier threshold. Such a methodology would result in an FY 2006 outlier threshold of $24,050. To account for the unspent outlier payments and attendant decreases in standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.***

By statute, Medicare provides extra payments for unusually high cost cases in order to limit hospitals' financial risk from extraordinary costs, and to diminish any financial incentive to avoid Medicare patients with especially serious illnesses.[10] These outlier payments are made only if the DRG payment, plus IME and DSH payments, plus any payments for new technologies, plus some fixed-loss cost outlier threshold (set annually by CMS) is exceeded. As required by statute, CMS sets the fixed-loss cost outlier threshold at a level that ensures that outlier payments constitute between 5 to 6 percent of total operating DRG payments plus outlier payments.[11] Also required by statute, CMS reduces the average IPPS standardized amount to account for the estimated proportion of total DRG payments made to outlier cases.[12]

In the proposed rule, CMS suggests setting the FY 2003 fixed-loss cost outlier threshold at $26,675, an increase of 3.3 percent from the FY 2005 threshold amount of $ 25,800. NAPH concurs with AHA's criticism of CMS' charge-inflation methodology used to justify such an increase and urges CMS to adopt a dual cost-inflation and charge-inflation methodology for calculating the outlier threshold. Such a methodology would result in an FY 2006 outlier threshold of $24,050.

[10] Social Security Act § 1886 (d)(5)(A).
[11] Social Security Act § 1886(d)(5)(A)(iv).
[12] Social Security Act § 1886(d)(3)(B).

Furthermore, NAPH believes the proposed increase in the outlier threshold is ill advised given that CMS has consistently over estimated the cost of outlier payments over the last few years and total outlier payments have accounted for less than the target amount of 5.1 percent of DRG payments. For example, using FY 2004 bills, outlier payments accounted for 3.5 percent of total DRG payments in FY 2004 and, in FY 2005, CMS projects that outlier payments will account for 4.4 percent of total DRG payments.[13] AHA data indicates that if CMS finalized the proposed threshold of $26,675, CMS will once again over estimate the expected cost of outlier payments and under spend by $510 million.[14]

An unwarranted policy that raises the outlier threshold unfairly penalizes hospitals with outlier cases that are already reporting losses from treating these high cost patients and will only have to expend more resources to reach the higher threshold. This policy is further exacerbated because CMS does not propose to retroactively adjust outlier payments or, in the alternative, standardized amounts, to ensure that payments for FY 2004 and FY 2005 are equal to the target of 5.1 percent of total DRG payments.

**NAPH opposes raising the outlier threshold. We support AHA's recommendation of utilizing a dual cost-inflation and charge-inflation methodology to calculate the outlier threshold. Such a methodology would result in an FY 2006 outlier threshold of $24,050. To account for the unspent outlier payments and attendant decreases in standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.**

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[13] Proposed Rule, 70 Fed. Reg. 23470.
[14] See Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 24, 2005).

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Transfers
Q Data
NT
ICD-9-CM
DRG/Recal
CAH Reloc
LTC-DRGs
Other/Ext Data

Hefler
Hartstein
Bodden
Krushat
Walz
Treitel
Brooks
Fagan
Kelly
Gruber
Hue
Collins
Morey
Smith
Hudson

June 22, 2005

***BY HAND DELIVERY***

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1500-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed rule**

Dear Dr. McClellan:

On behalf of the leading not-for-profit hospitals and health systems allied in Premier, I appreciate this opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule ("rule") on the Medicare Hospital Inpatient Prospective Payment Systems ("IPPS") for FY 2006, as published in the May 4, 2005 *Federal Register*.

Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and healthcare sites nationwide. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the IPPS, especially those involving drugs and medical devices.

Premier's principal recommendations and/or concerns are summarized below and discussed in the body of this letter.

- We believe that the procedures for data submission and validation should be improved for coherence and consistency, and that hospitals should not be penalized when technical issues outside their control impede data reporting.

- We adamantly oppose the expansion of the post-acute care transfer policy, which we believe is not in the best interests of patients or caregivers.

- We recommend that CMS increase the *new* technology add-on payment to 80 percent of the additional cost.

- We urge approval of at least two of the new technology applications for FY '06.

- We request that CMS implement the MMA requirement that qualifying *new* technologies be assigned to an appropriate existing DRG *first*, if possible; and that the agency clearly state that all special treatment of *new* technologies is exempt from budget neutrality adjustments, as required by the MMA.

- We urge CMS to proceed expeditiously with implementation the ICD-10 coding system.

- We are concerned about the proposed DRG classification changes for implantable cardiac defibrillators (ICDs), and urge CMS to *not* change the existing DRGs until better data are available. We believe the CMS proposal is based on flawed data.

- We urge you to make greater use of external data to facilitate public access to MEDPAR data. We are concerned that CMS no longer makes these data as available as necessary.

- We have several concerns about the impact that overly restrictive criteria for critical access hospitals (CAHs) designated as 'necessary providers' would have on patient care.

- We believe that CMS' proposed methodology for generating the long term care hospital (LTCH) re-weighting calculation would skew and undermine the prospective payment system.

## HOSPITAL QUALITY REPORTING

1. **Improve the procedures for data submission and validation for coherence and consistency, and do not penalize hospitals when technical issues outside their control impede data reporting.**

The ability of hospitals and their vendors to comply with the requirements for timely and accurate data submission has been challenged by miscommunication over data edits, technical ambiguities, and other issues. Therefore, Premier believes that the final rule governing the FY'06 Inpatient PPS should establish a clear documentation and communications process for this purpose. Additionally, Premier believes that hospitals should not be penalized when technical issues specific to the Centers for Medicare and Medicaid Services (CMS) or Quality Improvement Organizations (QIOs) hinder their ability to meet specific data requirements.

### Data Submission

- The parameters of the data submission process should be stated explicitly and documented. This includes exact specifications, all edits or audits to be applied, and other related information. Hospitals and their submission agents (vendors) must be privy to such parameters to ensure timely data submission. In addition, CMS should communicate any

changes to submission file requirements no less than 120 days prior to the effective/implementation date. No changes should be permitted once a submission quarter has begun, as this puts the integrity of the process at risk.

- For greater reporting accuracy, Premier believes that a test process for validating data file submissions and measuring calculations should be established. Hospitals and submission agents should be provided with a test file in the appropriate file specification format for internal verification *prior* to testing a submission. The process should permit submission of test file(s) to verify file formats, accuracy of data calculations, and other audit criteria related to data submission. An appropriate test process should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Alternately, if hospitals that do *not* sample elect to submit all of their qualifying cases for a given study (i.e., 425 pneumonia cases for a given quarter) and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that *every* one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

**Data Validation**

- The parameters of the validation process should be stated explicitly and documented. This includes clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well- documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. Premier proposes that any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- Premier believes that the validation process should incorporate *only* data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may earn an *overall* quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably *lower*. In this way, payments risk being based on inconsistent calculations and inaccurate data.

- The validation process is directed at medical record documentation and abstraction, not at the appropriateness of provided care. Consider, for example, the comparison of blood culture collection time, as documented by the RN, with the time printed on the corresponding lab report to verify data abstraction. The important point is that the blood

culture was drawn prior to the first antibiotic. Premier believes that ensuring patients' receipt of the right care at the right time should be incorporated into the validation process.

- Further, Premier believes that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data was submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

- Under the proposed rule, CMS only allows ten days for a hospital to appeal its validation; however, the agency fails to specify whether the reference is to "business" or "calendar" days. Premier believes that *neither* case offers sufficient time for hospitals to respond. Therefore, we propose allowing hospitals 30 calendar days to appeal their validation findings.

- Many Premier hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). Premier believes that all communications and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIOs) simultaneously. Such a strategy would simplify and standardize message generation. It would also eliminate the confusing and often contradictory communications typical of the current process, which requires state QIOs to interpret a given communication before forwarding it to hospitals.

## EXPANSION OF THE POST-ACUTE CARE TRANSFER POLICY

**2. Do not implement the proposed expansion of the post-acute care transfer policy. It is not in the best interests of patients or caregivers.**

Premier is adamantly opposed to the expansion of the post-acute care transfer policy, as outlined in the proposed rule. A policy expansion such as this would undercut the basic principles and objectives of the Medicare prospective payment system (PPS). The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs, while cases with shorter than average stays tend to be paid more than costs. An expansion of the transfer this policy makes it unlikely that hospitals would be able to break even on patients that receive post-acute care after discharge. Under the proposal, hospitals would "lose" whether a patient is discharged prior to or after the average length of stay.

The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the most appropriate care in the most appropriate setting. The policy disadvantages hospitals that make sound clinical judgments about the best care setting for patients, which is often outside of the hospital. Hospitals should not be penalized for greater than average efficiency. It is important to

understand that facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients would be disproportionately penalized under the proposed policy.

Again, expanding the transfer policy would undercut the basic principles and objectives of the Medicare PPS, undermine clinical decision-making, and penalize hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. This provision must be withdrawn in the final inpatient rule.

## PAYMENT FOR *NEW* TECHNOLOGIES

Section 503 of the Medicare Modernization Act of 2003 (MMA) provided new funding for add-on payments for new medical services and technologies, and relaxed the approval criteria under the inpatient PPS. This critical provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. Of the eight applications received for FY '06, CMS has proposed denying payment for five and has deferred decisions on the remaining three until the final rule. In sum, we believe the proposed rule raises a number of product and policy issues that may inappropriately deny new technologies their eligibility for payment. Premier is concerned that CMS continues to resist approving new technologies for add-on payments or DRG re-assignment.

### 3. Provide complete information on all new technology applications.

The proposed regulation does not provide complete information about applications in which CMS is proposing to consider the technology in question not *new*. Such decision are subject to comment, and as indicated below, Premier does not agree with CMS policies concerning determinations over the *"newness"* of technologies. We believe CMS should have also included in the proposed rule its preliminary decisions on whether an applicant technology is a "significant clinical improvement" and satisfies the cost threshold, as well as what the proposed add-on payment or special DRG assignment would be. We envision scenarios in which CMS states in the proposed rule that it does not consider a technology to be *new*, but then reverses its decision upon receiving comments. But then CMS could reject the application because the technology is not considered to be a "significant clinical improvement" or is deemed to not meet the cost threshold, in the agency's view. The public should be informed of the agency's views on all of the qualifying criteria so that all are open to public comment, as required by the Administrative Procedures Act.

### 4. Consider a technology to be *new* if the new ICD-9 code first took effect within the prior two-to-three years.

Premier believes that in making its decisions on the FY '05 and FY '06 new technology applications, CMS changed its policy concerning the "newness" of a technology. The agency asserts that the two-to-three year period of eligibility begins with the date of FDA approval, not the effective date of the ICD-9 code that specifically identifies the technology on the bill. In fact, this concept is embodied in the CMS regulations (42 CFR 412.87(b)(2)):

> *"A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service*

*or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)."*

Premier urges CMS to affirm a policy in which a technology qualifies as *new*, provided it is within three years after the effective date of the ICD-9 code. We ask that CMS reverse its position on the applicant technologies considered not *new* in the proposed rule because the agency used the FDA approval date as a marker, rather than the date of the new code.

**5. Increase the add-on payment percentage from 50 percent to 80 percent.**

The conference report accompanying the MMA urged CMS to increase the payment percentage for the additional cost of new technologies from 50 percent to 80 percent. (Eighty percent is the recognized payment percentage for inpatient outlier payments.) Premier notes that the payment percentage is specified in regulations and can, therefore, be altered without a change in law. The underlying statute requires the HHS Secretary to "provide for additional payment to be made ... with respect to discharges involving a new medical service or technology ... in an amount that adequately reflects the estimated average cost of such service or technology." Premier does not believe that payment at a 50 percent rate can be considered adequate, as it has commented in previous years. We request that CMS reconsider this payment rate in light of the conference committee's position and the statutory language.

**6. Implement the MMA requirement that qualifying *new* technologies be assigned to an appropriate DRG, if possible, before approving add-on payments.**

For technologies satisfying the cost criteria and other qualifying requirements under the inpatient *new* technology provision, the MMA requires that CMS *first* seek an appropriate temporary DRG, before establishing a new technology add-on payment. In the proposed rule, CMS correctly notes that amended section 1886(d)(5)(K) of the Act requires that prior to establishing an add-on payment for a new medical service or technology, the Secretary (of HHS) shall "seek to identify one or more DRGs associated with the new technology—based on similar clinical or anatomical circumstances and cost—and assign it to a DRG where the average costs of care most closely approximate the costs of care using the new technology. Within such groups, the Secretary shall assign an eligible *new* technology into a DRG in which the average costs of care most closely approximate the costs of care using the new technology..."

Premier is concerned that CMS does not acknowledge this statutory requirement in its response to a specific request for DRG reassignment by one of this year's *new* technology applicants (CHARITE Artificial Disk). In the proposed rule, CMS solicits comments on whether the agency should re-assign ICD-9-CM code 84.65 (Insertion of total spine disc prosthesis) to a new set of DRGs through the normal processes outside the context of the *new* technology DRG program. For example, the agency separates the two issues by stating it is "interested in public comments on both the new technology application for CHARITE and the DRG assignment for spinal disc prostheses." As we understand it, the applicant had requested DRG reassignment *within* the context of the *new* technology DRG application, as provided by the MMA amendments.

We encourage CMS to follow its statutory mandate and to first seek an appropriate, clinically similar DRG into which the applicant technology could temporarily be placed, prior to evaluating it for an add-on payment. While we recognize that it may not be possible to assign all eligible *new* technologies to existing DRGs, we believe CMS can more rigorously analyze, in accordance with its statutory mandate, whether an applicant new technology could be adequately reimbursed and appropriately classified in a temporary DRG assignment.

7. **Clearly indicate that all special payments for new technologies will be exempt from budget neutrality requirements.**

Prior to enactment of the MMA, the law required that additional payments for new technologies would be subject to the budget neutrality provisions of the prospective payment system. Section 503(d)(2) of the MMA removed this requirement with its injunction that "there shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act because an additional payment is provided under subsection (d)(5)(K)(ii)(III) of such section." CMS policy clearly provides that budget neutrality will not apply when add-on payments are made for *new* technologies, and it implies that the additional payments made as the result of a special DRG assignment also are exempt from budget neutrality, as the law requires. In other words, when a new technology qualifies for special treatment because it meets the three criteria, including that the payment rate would be inadequate if the technology were assigned to its "normal" DRG, then CMS is instructed first to consider a "special" DRG assignment and, if one is not possible, to make necessary add-on payments. Premier urges CMS to state clearly that additional payments made due to special DRG assignments, such as those for drug-eluting stents in 2003 and 2004, would be exempt from budget neutrality.

8. **Approve new technology treatment for spinal fusion and thoracic aneurisms**

Premier believes that two applications for special treatment as *new* technologies clearly satisfy the prescribed criteria, and would urge CMS to approve them as such for FY '06.

1) **CHARITE Artificial Disc.** CHARITE received an ICD-9-CM code on Oct. 1, 2004, and was approved by the FDA on Oct. 26, 2004. We believe that CHARITE clearly is a substantial clinical improvement over spinal fusion. Also, Premier believes that CMS' review must consider patients of all ages, not just patients over 60 years of age, recognizing that the Medicare program serves both aged and disabled beneficiaries. Finally, we repeat our earlier comment that CHARITE should be considered for assignment to the spinal fusion DRG, consistent with the MMA requirement to make a DRG assignment rather than an add-on payment where appropriate.

2) **Endovascular Graft Repair of Thoracic Aorta.** At the time of the manufacturer's initial application, FDA had not yet approved this device, but did so on March 25, 2005. CMS states in the proposed rule that FDA approval occurred too late for it to conduct cost threshold and significant clinical improvement analyses, but that it will do so for the final rule. Premier believes that this technology is clearly *new*, satisfies the cost threshold, and is a very "significant clinical improvement" because the affected patients currently need invasive surgery which is accompanied by a high mortality rate.

## IMPLEMENTATION OF ICD-10

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the conference language for the MMA, recommended that the HHS Secretary of Health and Human Services (HHS) undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technologies as required under the 2000 Benefits Improvement and Protection Act (BIPA).

To date, in spite of these recommendations, as well as those of several federal healthcare agencies and offices, and healthcare trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that without a change to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. Additionally, failure to recognize this looming problem will only impede efforts to achieve the President's goal for an electronic health record by 2014.

Premier urges CMS to proceed expeditiously to implement the ICD-10 coding system. We are concerned about the agency's ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes for identifying new health technologies and is in critical need of upgrading. Coding experts believe it is possible for ICD-9-CM to completely run out of new codes in less than 18 months. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule. Without the publication of even a proposed rule, the prospect of non-recognition of new major surgical procedures and entirely new medical technologies is a grim reality. It is imperative that the rulemaking process start immediately.

## CRITERIA FOR DRG CLASSIFICATION

### 9. Reject the proposed DRG changes for implantable cardiac defibrillators (ICDs) and maintain the current DRGs as currently structured.

We are concerned about CMS' proposal to remove hospital procedure code 37.26 (cardiac electrophysiological and recording studies [EPS]) from the list of cardiac catheterization procedures which map to DRGs 535 and 536. Because significant coding issues confound the use of code 37.26, we believe that code 37.26 should be retained in DRGs 535 and 536 until CMS resolves these issues and accumulates adequate data. These data would subsequently be used to determine whether a modification of the defibrillator DRGs is justified.

Currently code 37.26 covers a diagnostic electrophysiology study and a non-invasive programmed stimulation (NIPS). CMS is concerned that intraoperative device interrogation (currently included in code 37.94, ICD system implant) may also be commonly coded as 37.26. When one code embodies several disparate procedures with varying purposes, sites of service, and intensity, the resultant data is often not representative of any one of the procedures. Until the coding issues are addressed, the charge

data for cases in DRGs 535 and 536 involving 37.26 are invalid and should not be used as the basis for modifying the DRG assignments. The coding changes needed to eliminate the confusion surrounding code 37.26 were submitted to CMS on February 11, 2005, and will be on the agenda for the September 29, 2005, meeting of the ICD-9-CM Coordination and Maintenance Committee meeting.

Premier requests that CMS withdraw its proposal to remove code 37.26 from the list of cardiac catheterization procedures affecting the DRG assignment for defibrillator cases. Separate codes should be assigned to the separate procedures currently described by code 37.26. Charge data should be gathered for these distinct procedures to determine what type of modification, if any, of the DRGs is justified by the data.

## DATA ISSUES

### 10. Make greater use of external data and facilitate public access to MEDPAR data.

Premier is a major source of high quality data on hospital services, including both costs and outcomes, and we believe that these data (as well as that data available from many other organizations) can be used by CMS to establish Medicare policies. In certain areas, our data provide more detailed information than is available from MEDPAR. For example, Premier's data on drug-eluting stents include information on which were used, as well as the length and number of stents and vessels involved. CMS, however, continues to be reluctant to use external (i.e., non-Medicare) data. We believe CMS should work with industry to develop criteria for making greater use of external data.

We are also concerned about the difficulty the public experiences in obtaining MEDPAR data and the timeliness of such data. In the past, CMS has made the quarterly MEDPAR data update available to the public. For example, the public could obtain the September update of a particular fiscal year's MEDPAR data. While these data are incomplete, they contain reasonably complete information on discharges from the first six months of the fiscal year. As such, they can be useful in conducting analyses to provide input to CMS as it develops policies for the proposed rule. Premier requests that CMS resume making these quarterly updated files available. Finally, we are concerned that the MEDPAR data used to develop the proposed FY '06 rule was not made available until several weeks after its issuance, thus significantly reducing the public's ability to analyze the data and review and comment on policies in the proposed rule.

## CRITICAL ACCESS HOSPITALS (CAHs)

### 11. Replace the overly restrictive criteria applicable to replacement or relocation of a Critical Access Hospital (CAH) designated as a necessary provider.

Premier is concerned by CMS' proposal regarding the replacement or relocation of a CAH that has been designated as a necessary provider (NP). Many of the not-for-profit hospital systems allied in Premier have Critical Access Hospitals (CAHs) and could be adversely affected by this proposal. The

MMA repeals states' ability to grant necessary provider status as of Jan. 1, 2006, but allows any CAH to maintain such designation if included in its state's rural health plan before that date.

The proposed rule calls for rather restrictive criteria for the rebuilding or relocating of CAHs that are necessary providers, and we believe that these criteria do not reflect congressional intent. Specifically, the rule requires the necessary provider CAH to rebuild on the existing campus, within 250 yards of the current property or on a contiguous piece of property purchased prior to Dec. 8, 2003. This date is completely arbitrary; it is the date the MMA was signed into law and has nothing to do with necessary provider designations. Premier urges CMS to remove the date restrictions for relocations.

Many rural hospitals are in older buildings with dated floor plans, infrastructure and utilities. Newer facility designs promote patient safety and quality of care that would be, as a practical matter, prohibited by the proposed rule. Clearly, Congress did not intend to force these important providers to continue to care for patients in outdated facilities. Also, many rural hospitals are located on a small campus in the middle of residential neighborhoods, with relocation being the most appropriate, and sometimes only, alternative.

Because two-thirds of CAHs are necessary providers, these overly prescriptive requirements would place many rural communities at risk for losing access to crucial healthcare services—the very reason the CAH designation was created. Premier strongly believes that the requirements in the proposed rule are overly restrictive and could limit a necessary provider CAH's ability to improve access to care. We believe that a necessary provider CAH should be allowed to relocate within its current service area, and that reasonable criteria can be developed to effectuate such a policy.

## LONG TERM CARE HOSPITALS (LTCHs)

**12. The proposed rule would remove too many LTCH patients from the re-weighting calculation, thereby narrowing the pool of cases on which DRG relative weights are based, and eroding a fundamental feature of the prospective payment system—the principle of averaging.**

The proposed rule includes the recalibrated weights for the long term care hospital (LTCH) DRGs, which CMS estimates would reduce Medicare payments to LTCHs by $135 million in FY '06. When calculating the proposed weights, CMS used a new methodology that removed statistical outliers and cases with a LOS of up to seven days from the re-weighting calculation. In the proposed rule, CMS said that outlier cases were removed from the calculation because they "may represent aberrations in the data that distort the measure of average resource use" and that short-stay cases were removed since they "do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH." Premier is concerned that the proposed methodology inappropriately removes too many LTCH patients from the re-weighting calculation. By narrowing the pool of cases used to determine the relative weights for LTCH DRGs, the agency would erode a fundamental feature of the prospective payment system—the principle of averaging.

In closing, we appreciate this opportunity to comment on the FY '06 Hospital Inpatient PPS proposed rule. If you would like to discuss our comments further, or have questions, call me at 202-879-8003.

Sincerely,

Margaret R. Reagan

Margaret R. Reagan
Corporate Vice President
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Knight
Ellington
Treitel

AdvaMed
Advanced Medical Technology Association

June 21, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**File Code CMS-1500-P: Comments related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates**

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide our comment letter on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2006 rates (CMS-1500-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). AdvaMed is the largest medical technology trade association in the world, representing more than 1,300 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $75 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $175 billion purchased annually around the world. Nearly 70 percent of our members have fewer than $30 million in sales annually.

This letter reiterates and expands on some of AdvaMed's previously stated concerns about new technology add-on payments, including the definition of 'new' in the context of eligibility for new technology add-on payments. It also outlines our positions on a broad range of payment and policy issues contained in the Proposed Rule.

## New Technology Issues

Before we begin to discuss our comments to the Proposed Rule, we would like to make a few general comments regarding new technology add-on payments. We believe that the new-technology add-on program is an extremely important payment mechanism designed to ensure patient access to new medical services and technologies and to recognize the often higher costs of new technologies more quickly than would otherwise be possible through the underlying DRG system. AdvaMed has been one of the major proponents of this program and we have worked extensively with both Congress and CMS to create and improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies. AdvaMed and its member companies are committed to continuing to work with CMS to ensure that the program works as smoothly as possible.

CMS received eight applications for new-technology add-on payments in FY 2006. Of the eight applications, CMS proposed to deny payment for five products and deferred decisions on the remaining three until the final rule. While we are pleased that three applications remain under consideration, we also believe the Proposed Rule raises a number of product and policy issues that may inappropriately deny eligibility for a number of the remaining applications. In particular, we are concerned that the Proposed Rule raises issues regarding CMS's consistency on the definition of newness; the use of "substantial similarity" as a criterion in newness determinations; and implementation of certain provisions from the MMA. We provide detail on these and other concerns below, and request that you take these issues into consideration as you review all the applications for the final rule.

When new technologies are launched, manufacturers must rely on clear and definitive guidelines and processes to insure our reimbursement efforts and data collection meet the needs of CMS. If these guidelines are not clear, or are ever-changing, manufacturers lose valuable time in product adoption and patient access to life-changing technologies is greatly reduced. We respectfully request clarification on the issues noted below to ensure that the program requirements are as clear and predictable as possible.

*CMS Should Attempt to Assign New Technology to an Appropriately Clinically Similar DRG, Where the Average Costs of Care Most Closely Approximate the Costs of Care Using the New Technology ("New Technology Applications")*

For technologies satisfying the cost criteria and other qualifying requirements under the inpatient new technology provision, the MMA requires that CMS first seek an appropriate temporary DRG assignment before establishing a new technology add-on payment. In the Proposed Rule, CMS correctly notes that amended section 1886(d)(5)(K) of the Act requires that prior to establishing an add-on payment for a new medical service or technology, the Secretary (of HHS) shall "seek to identify one or more DRGs associated with the new technology, based upon **similar** clinical or anatomical circumstances and the cost of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. Within such groups the Secretary shall assign an **eligible** new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care using the new technology..." (emphasis added).

However, CMS does not seem to acknowledge this statutory requirement in response to a specific request for DRG reassignment by one of this year's new technology applicants (CHARITE Artificial Disk). In the Proposed Rule CMS solicits comments on whether the agency should re-assign ICD-9-CM code 84.65 (Insertion of total spine disc prosthesis) to a new set of DRGs through the normal processes outside the context of the New Technology DRG program. For example, the agency separates the two issues by stating it is "interested in public comments on **both** the new technology application for CHARITE **and** the DRG assignment for spinal disc prostheses." (emphasis added). We

understand the applicant has requested DRG reassignment within the context of the New Technology DRG application.

We encourage CMS to follow its statutory mandate and attempt to first seek an appropriate, clinically similar DRG on a temporary basis into which the eligible applicant could fit, prior to considering the technology for an add-on payment. While we recognize that it may not be possible to assign all new eligible new technologies to existing DRGs, we do think CMS should more rigorously analyze, in accordance with its statutory mandate, whether an applicant meets the test for the temporary DRG assignment in the Proposed Rule.

*CMS Has Been Inconsistent in Determining the End-Point to Eligibility for New Technology Payments ("New Technology Applications")*

CMS has been inconsistent in the manner in which it recognizes the reimbursement period for new technology, particularly when the payment eligibility period overlaps into a portion of another calendar year. In the Proposed Rule, CMS notes that a hip replacement product was available on the market in April 2003 and thus "charges reflecting the cost of the device may have been included in the data used to calculate the DRG weights in FY 2005 and the proposed DRG weights for FY 2006." CMS's preliminary conclusion is inconsistent with the agency's past rulings on other technologies, which were available on the market for nearly identical lengths of time as the hip replacement technology, and were approved by the agency for add-on payments.

Specifically, last year CMS approved add-on payments for cardiac resynchronization therapy with defibrillator (CRT-D). One such device received Food and Drug Administration (FDA) approval in May 2002, and another received FDA approval in June 2002. Both of these devices were deemed "new," since, according to CMS, the FY 2005 add-on payment year would represent the third year of the two-to-three year "new" window following the date of FDA approval. In addition, as CMS characterizes last year's decision on the CRT-D add-on payment in this year's Proposed Rule, "We also noted that we would extend new technology add-on payments for the entire FY 2005 even though the 2-3 year period of newness ended in May 2005 for CRT-D since predictability is an important aspect of the prospective payment methodology and, therefore, we believe it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year."

CMS also approved add-on payments in FY 2005 for Bone Morphogenetic Proteins (BMP) for spinal fusions. This product received FDA approval in July 2002 and, according to CMS, "[It] was still within the 2-year to 3-year period during which a technology can be considered new under the regulations."

There appears to be no meaningful distinction between the timeframe at issue in the case

of the hip replacement technology in this year's Proposed Rule and the timeframes that existed in the cases of the CRT-D and BMP technologies. The hip product was available on the market in April 2003 and is being considered for an FY 2006 add-on payment. As with the two comparably approved add-ons, the hip product's two-to-three year period of newness would end in the middle of the third and final year of eligibility for an add-on payment. Under CMS's interpretation of its own regulations, not only is the hip product still within the two-to-three period during which a technology can be considered "new," it is eligible for an add-on payment for the full fiscal year. Moreover, it is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

*CMS Should Signal that Technologies don't Meet Eligibility Requirements in its Annual Hospital PPS Proposed Rule ("New Technology Applications")*

To qualify for a new technology add-on payment, an applicant must meet the eligibility criteria contained at 42 C.F.R. § 412.87(b)(2) and (b)(3). The eligibility criteria define when a specific service or technology will be considered new, and under what circumstances the applicant will meet the cost thresholds. Assuming the eligibility criteria are met, CMS then focuses on whether the applicant technology is a substantial clinical improvement over existing technologies (42 C.F.R. 412.87(b)(1)). CMS states in the Proposed Rule that "we do not make determinations about substantial improvement unless a product has already been determined to be new and meet the cost criterion."

AdvaMed believes that the regulatory process would be improved if CMS would signal new technology applicants in the Proposed Rule whether they are unlikely to meet the eligibility requirements. This would permit applicants the opportunity to specifically address eligibility concerns during the comment period, after the proposed rule is issued. To the extent CMS waits until the final rule to reveal concerns about an applicant meeting the eligibility criteria, applicants are effectively left with no regulatory mechanism to provide feedback to CMS, and must wait an entire year to address CMS's concerns. The consequence is that the applicant essentially loses a year of eligibility to receive the new technology payment.

AdvaMed recognizes that it may not always be practicable, based upon lack of information, or other reasons, for CMS to take a preliminary position regarding a particular technology's eligibility in the proposed rule. However, AdvaMed believes that CMS often has at its disposal sufficient information to articulate at least a preliminary stance on eligibility when it issues the proposed rule. To the extent CMS has eligibility concerns, it should articulate them in the proposed rule and not wait until the final rule.

In such cases, AdvaMed requests that CMS more aggressively engage in dialogue with the industry and make its position known in the proposed rule.

*CMS Should Raise the New Technology Add-On Payment Percentage From 50% to 80% ("New Technology Applications")*

The MMA's report language urged CMS to consider raising the add-on payment level from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure with the new technology. We were disappointed that CMS did not address this issue in the Proposed Rule, but hope that CMS will consider this as a future change, so that the add-on payment is conformed to the inpatient outlier payment level.

*CMS Should Not Use Substantial Similarity as an Additional Criteria in the New Technology Add-On Process ("New Technology Applications")*

A new technology applicant must meet three criteria ('eligibility criteria') to be eligible for the add-on payment. The criteria at 42 C.F.R. § 412.87(b)(2) and (b)(3) – related to newness and adequate reimbursement under existing DRG payments – have been described in the past by CMS as 'threshold criteria.' The newness and cost threshold criteria must be met before CMS will analyze whether the technology is a substantial clinical improvement over existing technologies, as required by 42 C.F.R. § 412.87(b)(1).

CMS has in the past expressly avoided making determinations on the key clinical issue, substantial improvement, in circumstances where the new technology applicant does not meet the newness and cost criteria. For example, in the FY 2005 Final Rule, in response to its decision not to discuss the substantial clinical improvement criteria with regard to one applicant, CMS stated "[w]e conduct sufficient analysis on each application in order to provide sufficient opportunity for comment. We do not believe that it is necessary to provide a full analysis of all the criteria in cases where, for example, we believe that sufficient criteria is available in order to propose denying the application on the basis of the newness criterion." 69 Fed. Reg. 49018-49019 (Aug. 11, 2004). And, in the Proposed Rule for FY 2006, CMS reiterated that, "we do not make determinations about substantial improvement unless a product has already been determined to be new and meet the cost criterion."

The threshold criteria neither include criteria for determining whether a technology is substantially similar to existing technology, nor do they even address that issue. Nonetheless, in the Proposed Rule, CMS opines that several new technology applicants are 'substantially similar' to existing technology in the absence of any clinical assessment. AdvaMed is concerned that CMS is using the determination of 'substantial similarity' as a basis to support a preliminary determination that these technologies are 'not new,' and therefore not eligible for the add-on payment, when no such requirement exists in the threshold criteria, and even when the products fall within the two- to three-year window to be considered new by CMS's criteria.

AdvaMed believes this type of analysis is a departure from CMS's past practices, and amounts to the application of a barrier that is not contained within the threshold criteria of 42 C.F.R. § 412.87(b)(2) and (3). AdvaMed is also concerned that CMS is imposing criteria that are either intended to be applied, or at least similar to, the clinical criteria that should be addressed at the final stage, not the threshold stage, of the new technology application process. CMS has always clearly delineated that it does not wish to engage in assessing clinical improvement until such time as the cost and newness issues are decided favorably. In the Proposed Rule, however, CMS appears to be engaging in at least some form of a clinical analysis when it opines that a bone growth factor product is 'similar' to another product.

AdvaMed's concerns are magnified by the fact that the regulations contain no stated criteria for determining whether a technology is 'substantially similar' to another, and, further by the fact that the regulations make no mention of a substantial similarity test within the threshold criteria. While CMS did solicit comments prior to the February 23, 2005 Town Hall meeting on the topic of when products should be considered 'substantially similar,' the agency has not implemented such criteria by regulation, and in the Proposed Rule rejected many possible criteria that were suggested at that meeting.

AdvaMed does not believe that the determination of whether a technology is substantially similar is a part of the threshold criteria. Instead, such determinations are more properly conducted within 42 C.F.R. § 412.87(b)(1) which states that "[a] new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." We do not believe it is appropriate for CMS to adopt or undertake an ad hoc clinical assessment during the eligibility phase of the new technology application process.

*Eligibility of Add-on Payments for Subsequently Approved Products ("New Technology Applications")*

We wish to call to CMS's attention an apparent inconsistency in the application of the "substantial similarity" provision regarding the eligibility of competing products for add-on payments. In numerous instances, CMS has stated that "an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology" (May 4, 2005 Federal Register, page 23363). AdvaMed remains broadly supportive of this policy and believes it advances the goal of earlier patient access to new technology (despite our concerns with CMS' usage of "substantial similarity" as noted above).

AdvaMed is therefore surprised by CMS's statement that thoracic aortic stent grafts that are approved by the FDA subsequent to the FDA's approval of W.L. Gore & Associates' Endovascular Graft Repair of the Thoracic Aorta (GORE TAG) – which submitted the

new technology application – may only be considered as eligible for an add-on if the product receives FDA approval prior to publication of the FY 2006 rule (May 4, 2005 Federal Register, page 23363). It appears that imposing a requirement of FDA approval for subsequent products prior to an arbitrary date, such as the publication of the final rule, contradicts CMS's goal of not bestowing an advantage to the first product to reach the market. In addition, since all endovascular stent grafts for thoracic aneurysm will be identified by the same new ICD-9-CM procedure code, CMS will be operationally incapable of determining which products are eligible for add-on payments and which ones are not. We therefore urge CMS to revise its stated position on eligibility for add-on payments and clarify that the subsequent date of FDA approval for "substantially similar" thoracic endografts will have no bearing on whether such products are eligible for add-on payment if the initial applicant is approved.

**DRG Reclassifications Issues**

*Stroke Reimbursement ("DRG Reclassifications")*

AdvaMed applauds CMS for meeting with industry representatives from several hospital stroke centers and seeking comment on their recommended modification of the existing stroke DRGs 14 and 15 by using the administration of reperfusion agents as a proxy to identify patients who have severe stroke. Cases that involve reperfusion agents such as thrombolytic therapy are highly resource intensive, as shown in CMS's analysis. To ensure that Medicare resources are allocated efficiently to the most severe stroke discharges, we recommend that CMS create a separate DRG for patients receiving a reperfusion agent outside of the existing DRGs 14 and 15. AdvaMed notes that Medicare hospital reimbursement for stroke-related procedures has historically been relatively poor. Accordingly, AdvaMed supports the proposed modifications to DRGs 14 and 15 that would improve reimbursement and patient access to the most efficacious therapies for stroke patients who are disproportionately covered by Medicare. CMS's timely attention towards DRG restructuring will dramatically improve the barriers faced by hospitals today in providing these treatments, thereby improving patient outcomes for this urgent disease state.

*Automatic Implantable Cardioverter/Defibrillator ("DRG Reclassifications")*

We ask CMS to withdraw its proposal to remove hospital procedure code 37.26 (cardiac electrophysiological and recording studies [EPS]) from the list of cardiac catheterization procedures that map to DRGs 535 and 536. We believe that code 37.26 should be retained in DRGs 535 and 536 until CMS clarifies coding issues surrounding code 37.26 and accumulates adequate data to determine whether a modification of the defibrillator DRGs is justified.

Currently code 37.26 covers a diagnostic electrophysiology study and a non-invasive

programmed stimulation (NIPS). CMS is concerned that intraoperative device

interrogation (currently included in code 37.94, ICD system implant) may also be commonly coded as 37.26. When one code embodies several disparate procedures with varying purposes, sites of service, and intensity, we believe the resultant data is not representative of any one of the procedures. Until the coding issue is addressed, the charge data for cases in DRG 535 and 536 involving 37.26 is invalid and should not be used as the basis for this proposed modification. The coding changes needed to eliminate the confusion surrounding code 37.26 were submitted to CMS on February 11, 2005, and will be on the agenda for the September 29, 2005, meeting of the ICD-9-CM Coordination and Maintenance Committee meeting.

CMS should withdraw its proposal to remove code 37.26 from the list of cardiac catheterization procedures that affects the DRG assignment for defibrillator cases. Separate codes should be assigned to the separate procedures currently described by code 37.26. Charge data should be gathered for these distinct procedures to determine if the data justifies a modification of the defibrillator DRGs. Once coherent charge data has been collected, we would welcome the opportunity to evaluate future refinement of the current defibrillator DRGs based on appropriate resource utilization.

*Coronary Artery Stents ("DRG Reclassifications")*

AdvaMed supports CMS as it continues to maintain a separate reimbursement structure for discharges involving the insertion of drug-eluting coronary artery stents (DES). This temporary structure has allowed hospitals to obtain some incremental reimbursement for the more costly DES cases as compared to patients receiving bare metal stent (BMS) devices. While hospital utilization of BMS devices has declined, CMS should not eliminate the temporary DES DRGs until such time that BMS represent an insignificant proportion of the total coronary stent discharges.

CMS has proposed to modify this structure in FY 2006 by splitting out the two existing coronary stent DRGs for AMI patients (516 and 526) based on the presence or absence of a secondary diagnosis on the existing CC list. Specifically, CMS is proposing to delete DRGs 516 and 526 and replace them with four DRGs: DRG 547 (Percutaneous Cardiovascular Procedure with AMI with CC), DRG 548 (Percutaneous Cardiovascular Procedure with AMI w/out CC), DRG 549 (Percutaneous Cardiovascular Procedure with DES with AMI with CC and DRG 550 (Percutaneous Cardiovascular Procedure with DES with AMI w/out CC).

As exhibited in the FY 2004 MedPAR file, there is a clear differential in the average hospital charges for AMI patients with and without CCs. AdvaMed supports the creation of the four new DRGs for FY 2006 that would differentiate reimbursement for these sets of AMI patients which represent approximately 27 percent of all coronary stent discharges. At the same time, AdvaMed, agrees with the agency that this structure should "not preclude proposals in subsequent years to restructure the coronary stent

DRGs based either or both on the multiple vessel treatment or insertion of multiple stents."

AdvaMed congratulates CMS for acting quickly to create four new ICD-9-CM codes identifying multiple stent insertion (codes 00.45, 00.46, 00.47 and 00.48) and four new codes identifying multiple vessel stent (MVS) treatment (codes 00.40, 00.41, 00.42 and 00.43). We believe these codes will provide CMS with important data as it continues to analyze and refine both coronary and peripheral stent DRGs. AdvaMed looks forward to working with the agency as the data from these new multi-vessel/multi-stent codes become available.

The creation of four new DRGs and eight new ICD-9-CM procedure codes related to coronary and peripheral vascular stenting in FY 2006 may present challenges for hospitals initially when billing and coding for DES procedures. We encourage CMS to support collaborative education efforts with the American Hospital Association Coding Clinic to ensure that hospitals are aware of the new codes and DRGs. AdvaMed members also plan similar education efforts to ensure that the data derived from the new codes is accurate.

*Carotid Artery Stents ("DRG Reclassifications")*

As the agency notes in the Proposed Rule, CMS established codes for carotid artery stenting procedures (CAS) on October 1, 2004. AdvaMed commends CMS and the ICD-9-CM Coordination and Maintenance Committee for working with industry to create these new procedure codes to properly identify and track this breakthrough therapy.

For the Proposed Rule, CMS completed an analysis using FY2004 MedPAR data to determine charges and length of stay associated with carotid artery stenting in DRGs 533 and 534 by using procedure codes 39.50 and 39.90 in combination with diagnosis code 433.10. This code combination is an excellent proxy to identify carotid stenting cases given that the new ICD-9 codes were not effective for the FY2004 MedPAR data. The analysis of FY2004 MedPAR indicates that carotid artery stenting cases have average charges of $29,737 and $22,002 for DRG 533 and 534, respectively, compared to average charges of $24,464 and $15,873 for all cases within DRG 533 and 534, respectively, resulting in charge differentials of $5,273 (22%) and $6,129 (39%).

In analyzing the FY2004MedPAR data, we noted an even greater difference in average charges between carotid stent cases and the average charge for the entire DRG as evidenced in the table below:

| DRG | With or without 39.50 and 39.90 | Discharges | Average Length of Stay | Average Charge | Average Standardized Charge |
|---|---|---|---|---|---|
| 533 | All Cases | 35,730 | 3.1 | $ 23,910 | $ 21,286 |
| 533 | DRG without codes 39.50 and 39.90 | 33,992 | 3.1 | $ 23,294 | $ 20,845 |
| 533 | DRG with codes 39.50 and 39.90 | 1,738 | 3.1 | $ 35,961 | $ 29,903 |
| 534 | All Cases | 37,457 | 1.7 | $ 17,012 | $ 15,166 |
| 534 | DRG without codes 39.50 and 39.90 | 35,911 | 1.7 | $ 16,580 | $ 14,870 |
| 534 | DRG with codes 39.50 and 39.90 | 1,546 | 1.5 | $ 27,042 | $ 22,065 |

Based on analysis of the MedPAR data, the increase in charges between carotid stent cases and DRGs 533 and 534 is $8,617 (40%) and $6,899 (45%), respectively, indicating the potential for significant under payment for carotid stenting cases in these DRGs. This potential underpayment for carotid stenting procedures is likely understated as the 2004 MedPAR data came at a time prior to FDA approval of any carotid devices and thus only included discharges for patients participating in clinical trials. As a result, it is likely that few, if any, hospitals included the full cost, or any significant cost, of the carotid stenting devices in their FY 2004 charges. The differential between carotid and non-carotid cases will likely grow more pronounced in the FY 2005 MedPAR data as hospitals begin to include the charges for the FDA-approved carotid stent cases in their claims to CMS.

Although, we appreciate CMS' attention to establishing the appropriate payment for this technology, given the significant difference in charges, we recommend that CMS create new DRGs for carotid stenting cases, split on the presence or absence of complications or co-morbidities. In the analysis, the volume of carotid artery stent cases appears small, but, given the recent availability of FDA approved devices new and ongoing clinical trials, multiple post market registries, and expanded Medicare coverage the volume of carotid stent cases is and will continue to increase. The increase in patient volume and the inadequate payment for carotid artery stent cases will create a financial hardship on facilities providing this technology, potentially resulting in decreased beneficiary access to a beneficial therapy. Therefore, we encourage the agency to consider a new DRG pair for carotid artery stenting in FY 2006.

*Hip and Knee Replacements -- DRG Split of Revision Procedures ("DRG Reclassifications")*

AdvaMed commends CMS for its efforts to provide appropriate payment for revision hip and knee arthroplasty by proposing to split DRG 209 into DRG 544 (primary hip and knee arthroplasty) and DRG 545 (revision hip and knee arthroplasty), and to expand the scope of the relevant ICD-9-CM procedure codes. The new codes, in particular, are an important component in aligning hospital reimbursement with hospital costs and patient

benefits of total joint arthroplasty. We look forward to working with CMS to ensure that total joint arthroplasty procedures are tracked properly and paid for appropriately in the future.

We would encourage CMS to engage in dialogue with industry and providers regarding further DRG changes related to primary joint arthroplasty procedures, which represent approximately 90% of total hip and knee arthroplasty procedures. We are concerned about the unintended consequence of curtailing both medical technology innovation and limiting Medicare patient access to continued advances in treatment related to joint arthroplasty.

Industry is committed to continuously improve medical technologies used in joint arthroplasty. These improvements offer better outcomes to Medicare patients, and extend implant survivorship, which help reduce the need for future revision procedures. We look forward to providing guidance and support to CMS with regard to any further changes to DRGs related to total hip and knee arthroplasty procedures.

*Comprehensive Review/Refinement of Complications/Comorbidities List ("DRG Reclassifications")*

We agree with CMS that changes in resource utilization and in inpatient hospital care, particularly the focus on decreasing length of stay, may be resulting in the complications/comorbidities (CC) distinction not being able to differentiate resource utilization and patient severity as well as it has in the past. We also agree that it may be valuable to conduct a substantive and comprehensive review of the CC list for the future. However, we caution the agency to conduct this review with as much transparency and stakeholder involvement as possible and not to rush its analysis simply to meet the deadline for the FY 2007 rule. In fact, the agency may find it apparent when it begins to undertake its review and revision of the CC list that attempting to revise the CC list for the FY 2007 rule may be an unrealistic goal and additional time may be required, particularly to ensure stakeholder involvement in the review and revision.

In the Proposed Rule, CMS provides several examples of how the standards for determining the list of CCs might be revised. We recommend that CMS analyze several methodologies and publicly disseminate both the methods tested and the results of the analysis for comment. The final methodology, standards and final CC list should also be subject to public comment with sufficient time to allow for significant changes if needed before implementation in the final rule, thus, they should be released well ahead of the proposed inpatient rule for FY 2007. We encourage CMS to evaluate both the potential impact a secondary diagnosis may have on length of stay and on hospital charges as well as a comparison of the CC lists used with other DRG systems. The revision of the CC list will potentially have an extensive impact on hospital revenue streams, so any review and revision should be completed and implemented cautiously, systematically and thoroughly, using external expertise and maintaining transparency and stakeholder involvement throughout the process.

**Post Acute Transfer Policy Issue**

*Post Acute Transfer Policy ("Post Acute Care Transfers")*

We commend CMS for continuing to refine the DRG payment methodology to more appropriately align patient severity and facility resources with reimbursement. While the Post Acute Transfer policy may achieve efficiencies for some types of care, AdvaMed is concerned about the potential that it could undermine hospital incentives to shorten patient lengths of stay. As a result, more patients could be retained, for longer periods of time, in expensive acute short stay hospitals. We suggest, however, that it is premature to significantly increase the number of DRGs subject to the Post Acute Transfer Payment Policy since the reimbursement methodologies and treatment have changed significantly since 1998 when the policy was first implemented. AdvaMed is concerned that the criteria for Option 1 and Option 2 are based only on statistical analysis of postacute discharges or relationship to another DRG rather than a review of clinical treatment provided in the first and second days of an admission. As a result, the selection of DRGs is inconsistent and contradictory to the goal of aligning patient severity with payment.

To illustrate, of the 231 Post Acute Transfer DRGs, 58, or 25%, have a Geometric Mean Length of Stay (GMLOS) of less than 3.0 days which contradicts the criteria listed by CMS for Option 2. The policy to include a DRG "paired" with one that meets the criteria was based on a concern that is no longer valid, as most hospital coding systems interface to the billing system, and if the DRGs are paired with CCs, hospitals are not likely to delete the CC code. Secondly, the Transfer Policy allows for two types of payment to compensate for the higher intensity of first day care. However, there was no evaluation by CMS to determine if these payments are sufficient to cover that care. Although the Special Payment policy does provide that 50% of the DRG reimbursement be paid on the first day, it is not apparent from reading the Proposed Rule what criteria were utilized to select the DRGs subject to this policy. The result is inconsistent application. For example, DRG 109 (Coronary Bypass w/o PTCA or Cardiac Cath) is assigned the Special Pay policy while DRGs 107 (Coronary Bypass w PTCA) and 108 (Coronary Bypass w Cardiac Cath) will not be paid under the Special Policy. DRGs 107 and 108 are surgical types of DRGs in which the significant majority of resources are expended on the surgical procedures grouped to these DRGs, and therefore should be subject to the Special Payment policy.

AdvaMed notes that the basis for the post acute transfer policy was established on July 31, 1998 at 42 CFR § 412.4. The law that enacted this regulation was accompanied by "The Conference Agreement" in which the Conferees wanted "...strong incentives to treat patients in the most effective and efficient manner,....". At that time the policy went into effect, Medicare reimbursement for Post Acute Transfer services was based on costs. The current status has changed, and most of these services have transitioned to prospective payment systems (SNF PPS 10/1/1998; HHA PPS 10/01/2000; IRFS 01/01/2002; LTCH 10/01/2002; and IPF 01/01/2005). Medical technologies, innovative

treatment modalities, reimbursement policies and physician practice patterns have also significantly changed treatment delivery in a variety of settings since the initial regulations were implemented.

Since CMS has indicated in the Proposed Rule that it will be conducting an analysis of patient severity payment methodologies in response to the MedPAC recommendations, it would make sense to conduct the evaluation of the Post Acute Transfer Policy on DRG payments within that analytic framework. In the proposed rule of May 8, 1998, Appendix E provided cost analysis for each DRG subject to the Post Acute Transfer Policy. A review of a similar analysis and various severity adjustment methodologies may provide more appropriate alignment of payment with patient care and facility resource costs rather than adding additional payment rules that appear to have no clinical basis. We respectfully request postponing any change in the post acute transfer policy until a thorough analysis and review of severity methodology options is completed. We request that CMS undertake such changes only with ample notice and opportunity for meaningful comment from industry.

**Blood Reimbursement Issue**

*Blood Reimbursement ("Hospital Market Basket" and "Excluded Hospital Market Basket")*

As noted in the preamble to the Proposed Rule, CMS included in the FY 1997 based market basket a separate cost category for blood and blood products. This action was consistent with a 2001 MEDPAC Report to Congress entitled, "Blood Safety in Hospitals and Medicare Inpatient Payment." MedPAC made the following recommendation:

> When CMS revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

MedPAC noted in that report that blood and blood products were included as a separate cost category in the Market Basket prior to fiscal year 1997. The category was combined with the chemicals component beginning in fiscal year 1997 but was listed as a separate category again beginning in fiscal year 2003. MedPAC further noted that CMS's decision to add blood and blood products to the chemicals component was motivated by "a lack of appropriate data for calculating a weight for blood services."

AdvaMed notes that the basis for CMS's motivation to add blood and blood products to the chemicals component, i.e. a lack of appropriate data, no longer exists. CMS was not only able to calculate a weight for the 2003 market basket (0.875), but was also able to list the weight (1.082) in the Proposed Rule. We urge CMS to act in accordance with the MedPAC recommendation and retain blood and blood and blood products as a separate cost category in the Market Basket.

Additionally, we appreciate CMS's review of three alternative price proxies for blood and blood products. As noted in the Proposed Rule, CMS previously used the Bureau of Labor Statistics (BLS) PPI (commodity code #063711) for blood and derivatives as a price proxy. While we agree that price movements in the major component of the PPI for blood and derivatives recently were not consistent with trends in blood costs for all the products used by hospitals for inpatient care, we are not aware of data that would provide a basis for the assertion that the PPI for finished goods, less food and energy, has "moved most like the recent blood cost and price trends," as CMS states. CMS goes on to say that it believes that this index will "best be able to proxy price changes (not quantities or required tests) associated with blood purchased by hospitals," but fails to support its rationale in the Proposed Rule.

We request that CMS provide the public, in particular the blood banking community, with the data upon which CMS is making this judgment that blood costs most closely track finished goods costs. Absent disclosure and public discourse of convincing data, we believe that blood should not be moved temporarily to yet another unrelated category to which an unrelated PPI is being applied. Instead, AdvaMed supports the expeditious establishment of a new blood-related PPI that accurately tracks changes in blood costs that hospitals purchased for inpatient care. The BLS has begun work in creating this new PPI and we look forward to continued dialog and involvement with BLS and CMS on this initiative. We understand that these comments are consistent with those of AABB and other organizations representing blood stakeholders. AdvaMed fully supports such comments that are consistent with the language above.

## Additional Miscellaneous Issues

### *MedPAR Data Should be Released Earlier to Make it More Useful*

CMS uses the most current Medicare Provider Analysis and Review (MedPAR) data file in its process of drafting both the Proposed and Final Inpatient Rules, and releases current MedPAR data on a semi-annual basis. We remain concerned regarding the lack of availability to the public of current MedPAR data at the time that CMS requests public comment on both the Proposed and Final Inpatient Rules. In the past, and including the release of this most recent FY 2006 NPRM, CMS has only made the MedPAR data available to the public approximately two to three weeks prior to the close of the comment period. This year, the Proposed Rule was released on April 25, but MedPAR data was not released by CMS until more than a month later, on June 3, 2005. AdvaMed believes that CMS is able to and should make the MedPAR data available to the public for the **entire** comment period. Releasing the MedPAR data to coincide with the release of the requests for comments for both the Proposed and Final Rules will enable more complete responses to issues raised, and will ensure more meaningful dialogue between CMS and the public. We also believe that CMS should consider release of the MedPAR data on a more frequent, quarterly basis.

*CMS Should be Willing to Accept and Use External Data Submitted by the Public*

AdvaMed believes that CMS should be open to consider the use of external data to determine eligibility for new technology payment and also for determining the most appropriate initial DRG assignment for a new technology not eligible for add-on payment or for which an add-on payment application has not been filed. In the case of technologies that are not subject to add-on payment, CMS should consider using external data to assign a new technology to an appropriately paying DRG as soon as possible after FDA approval.

AdvaMed's February 15, 2005 Position Statement on External Data responded to CMS's request for greater clarification on the needs of industry in this area, and provided examples of specific situations in which external data could be utilized by CMS. The major points of the position paper were as follows:

1) CMS should acknowledge that different types of data are appropriate for different uses.
2) CMS should distinguish between proprietary data and publicly available data when requiring that external data be made available for public inspection.
3) When hospitals cannot be identified due to confidentiality agreements, CMS should be willing to accept external data that are denitrified by geographic location and pseudo-identifier.
4) CMS should allow the use of external data from recent timeframes without corresponding MedPAR data, particularly for those procedures involving new technologies and codes.
5) When a company submits external cost data to CMS, CMS should accept the disclosure of discount and rebate data at the estimated aggregate level.
6) CMS should request that medical technology companies offer the typical device-related HCPCS and ICD-9 codes that seem most clinically appropriate to a particular procedure.

*ICD-10 Implementation Should Proceed as Expeditiously as Possible*

The MMA's report language urged CMS to move forward with the implementation of ICD-10 as quickly as possible. While we understand that there are many complexities involved with the transition from ICD-9 to ICD-10, it is also our understanding that the number of available codes under ICD-9 is rapidly dwindling and that the availability of new codes has been raised in public meetings as a potential basis for CMS to deny applications for new codes. AdvaMed notes that in 2003, after several years of hearings, the National Committee on Vital and Health Statistics (NCVHS) raised concerns about the viability of the ICD-9-CM as it was 'increasingly unable to address the needs for

accurate data for health care billing, quality assurance, public health reporting, and health services research.' NCVHS also noted in 2003 that these concerns have been 'well documented' in the testimony and letters provided to the NCVHS over the past several years. NCVHS recommended in 2003 that HHS act expeditiously to initiate the regulatory process for adoption of ICD-10CM and ICD-10 PCS.

While the NCVHS acknowledged that the migration to ICD-10 was potentially complex, it also indicated it was 'in the best interests of the country' to replace ICD-9 with ICD-10, and recommended in 2003 that HHS move forward expeditiously with initiation of the regulatory process for full implementation. As of 2005, we are still awaiting a process from HHS to begin this important transition. In the meantime, ICD-9 is quickly becoming outdated because of the lack of codes left to identify new procedures and new technologies. We note that at the March 30, 2005 meeting of the ICD-9-CM Coordination and Maintenance Committee, a number of comments were made objecting to the issuance of certain new procedure codes for new services and technologies. The concerns raised at the meeting mentioned the lack of availability of new codes within the ICD-9-CM. Several commenters appeared to be advocating a higher threshold for the award of new codes based on the ever decreasing number of available codes under ICD-9-CM. AdvaMed is very concerned that reluctance to issue new codes will hinder appropriate tracking, identification, and analysis of new medical services and technologies. ICD-10 is the next generation of coding system, and would modernize and expand CMS's capacity to keep pace with changes in medical practice and technology. Its unique structure would incorporate all new procedures as unique codes that would explicitly identify the technology used to perform the procedure. AdvaMed accordingly requests that CMS move forward with implementation of ICD-10 as quickly as possible.

*CMS's Response to MedPAC Recommendations ("MedPAC recommendations")*

MedPAC has recently made a number of recommendations to the hospital inpatient PPS reimbursement system. Although broad in scope, the MedPAC recommendations are designed to address reimbursement issues that arise in the context of reimbursement for specialty hospitals. According to GAO, as of February 2003, the year CMS first imposed the moratorium, specialty hospitals numbered only 92 nationwide, and as of FY 2000, accounted for less than 1 percent of Medicare spending for inpatient services. AdvaMed is concerned about the potential for disruption and unintended consequences that may result from making fundamental changes to the entire Medicare hospital inpatient PPS system based on irregularities that are purportedly occurring in such a small percentage of hospitals nationwide. Perhaps further study could result in a mechanism that would more specifically target the aspects of concern.

Included in MedPAC's recommendations addressing specialty hospitals are the replacement of DRG charge-based weights with cost-based weights, the use of hospital-specific relative weights, the replacement of DRGs with severity-based APR-DRGs, and DRG-specific outlier reductions. These proposed changes have the potential to cause enormous and unpredictable effects to hospital inpatient PPS reimbursement. AdvaMed

notes that the MedPAC recommendations focus on changes to the entire PPS systems based on a perceived problem with a relatively small subset of claims related to specialty hospitals. Moreover, in advocating that its proposed changes be implemented incrementally, over a lengthy time, MedPAC is tacitly acknowledging the potential for unpredictable and potentially undesirable effects of these comprehensive changes.

In the Proposed Rule, CMS mentions several potential issues that would arise and/or make it difficult to currently implement the MedPAC recommendations, including difficulties in obtaining current cost to charge data, and charge compression if hospital-specific weights are adopted. AdvaMed echoes CMS's concern regarding the difficulties in obtaining current cost to charge data. Assuming the MedPAC recommendations become slated to be implemented, it is essential that this concern be addressed prior to the implementation. In the outpatient setting, the calculation of the Ambulatory Payment Classification (APC) rates for outpatient PPS system has, from its inception, been hampered by significant omissions in the claims data, especially for device-related services. While CMS has attempted to modify its rate calculation methodology, there have been longstanding problems in the outpatient PPS system related to shortcomings in data. AdvaMed therefore is in full agreement with CMS's reservations regarding the feasibility of implementing MedPAC's recommendations given the difficulties of obtaining current cost to charge data. AdvaMed also agrees that any approach to significantly modify the inpatient PPS system should come only after CMS takes a measured, studied, and fully transparent approach to address these issues.

As we discussed in a prior section in this letter, CMS has indicated that it intends to undertake a comprehensive and systematic review of the complication/comorbidity list for the 2007 IPPS rule. CMS has also stated that it may undertake a selective review of specific DRGs that are cited by MedPAC as problematic. AdvaMed believes that CMS should complete these projects before considering whether to implement the MedPAC proposals. AdvaMed also agrees with CMS that further detailed examination and analysis of the MedPAC proposals, the potentially disruptive effects of the proposals, and careful examination and study of alternatives, are warranted at this time.

Please contact us directly if you have any questions on the letter. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

David H. Nexon
Senior Executive Vice President

Cc: Thomas A. Gustafson
Liz Richter
Marc Hartstein
Herb Kuhn

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JUN 24 2005

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Temple University Health System

3401 North Broad Street
Philadelphia, PA 19140-5189

IME
GME/AFF

Hefter
Hartstein
Lefkowitz
Ruiz
Truong

June 20, 2005

Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Re: CMS - 1500 – P – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

[GRADUATE MEDICAL EDUCATION]

Dear Dr. McClellan:

On behalf of the Temple University Health System (TUHS) and its member institutions Temple University Hospital (TUH), Temple University Children's Medical Center (TUCMC), Jeanes Hospital, and Temple East/Northeastern Hospital (collectively, the TUHS Affiliated Group), we are pleased to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates as published in the May 4 *Federal Register*.

Our comments in this letter are limited to those portions of the proposal concerning changes to the IME adjustment, (beginning at FR 23440). In particular, we respond to CMS's proposal to allow new urban teaching hospitals to enter into a Medicare GME affiliation agreement under certain circumstances.

In the proposed rule, CMS states:

> We are proposing to revise §413.79(e)(1)(iv) so that new urban teaching hospitals that qualify for an adjustment under §413.79(e)(1) may enter into a Medicare GME affiliation agreement under certain circumstances. Specifically, a new urban

teaching hospital that qualifies for an adjustment to its FTE caps for a newly approved program may enter into a Medicare GME affiliation agreement, but only if the resulting adjustments to its direct GME and IME caps are "positive adjustments." "Positive adjustment" means, for the purpose of this policy, that there is an increase in the new teaching hospital's caps as a result of the affiliation agreement. At no time would the caps of a hospital located in an urban area that qualifies for adjustment to its FTE caps for a new program under §413.79(e)(1), be allowed to decrease as a result of a Medicare GME affiliation agreement. We believe this proposed policy change would allow new urban teaching hospitals flexibility to start new teaching programs without jeopardizing their ability to count additional FTE residents training at the hospital under an affiliation agreement.

We interpret this proposed change as allowing TUCMC to continue its present membership in the TUHS Affiliated Group, even after the establishment of a new pediatric residency program at TUCMC, provided that none of the new residency slots at TUCMC are at any point allocated to Temple University Hospital or another member of the TUHS Affiliated Group.

**TUHS has actively advocated for such a change to CMS's policy and we strongly applaud CMS's proposed modification. We believe this change would correct an unintended consequence of the present statute and remove a barrier to the expansion of vital and critically important teaching programs.**

Thank you for your continued efforts to protect the integrity of the Medicare program and your consideration of our concerns.

Respectfully,

Raymond Uhlhorn

Raymond Uhlhorn

**Headquarters**
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JUN 24 2005
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**Government Affairs Office**
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NATIONAL RURAL HEALTH ASSOCIATION

CAH Reloc
WI/OM
Transfers
SCH
DSH
Geo Reclas

Hefter
Hartstein
Collins
Morey
Smith
Miller
Walz
Hart
Navarro
Smith
Kenley

June 23, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850.

**Reference: CMS-1500-P**

Dear Administrator McClellan:

The National Rural Health Association (NRHA) appreciates the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems and fiscal year 2006 rates published in the *May 2005* **Federal Register**. We appreciate your ongoing commitment to rural health care, and the NRHA looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans.

The NRHA is a national nonprofit membership organization that provides leadership on rural health issues. The association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership is made up of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.

Of particular concern to NRHA is the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

Or comments are as follows:

**CAH Replacement Facilities**

1.) **We strongly oppose all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule.**

2.) **The proposed "75% threshold" is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original Necessary Provider designation,** i.e. that the "CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees."

Our basis for this position is as follows:

1. The Proposed Regulation transfers to the Centers for Medicare and Medicaid Services (CMS) control over the basic structure of local rural health care, a loss of local control never before seen, and if allowed to stand, a precedent that threatens all hospitals and all communities.

2. It was clearly not the intent of Congress in the Medicare Modernization Act that a Critical Access Hospital (CAH) designated as a Necessary Provider be perpetually prohibited from replacing or relocating their facility, facilities that are often 40 to 50 years old.

3. Many rural hospitals are located on a small campus in the middle of residential neighborhoods with relocation being the most appropriate, and sometimes only, alternative since there is no room to expand on the existing facility.

4. The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money to assets to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more over time, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly cost of rebuilding. The proposal then displays a short sighted thinking process by the rule makers and a dramatic misunderstanding of the health care setting in rural areas.

5. Many rural hospitals are in 40-50 year buildings with antiquated floor plans, construction and utilities. Newer facility designs promote patient safety and quality of care that would be, as a practical matter, prohibited by the proposed rule. Forcing hospitals to continue in outdated facilities is an inappropriate and avoidable risk for rural communities.

6. A ban on major construction projects developed after December 8, 2003 is an over reaction against a potential problem that can be appropriately managed by the portion of CMS's proposed rule that would require assurance that, after the construction, the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff.

7. The CMS ban is based on the misguided belief, not tested in law and a break with CMS's past policy that the relocation of a CAH can be treated differently than the relocation of any other hospital. There is no basis in law that the relocation within a community of a CAH with Necessary Provider status constitutes a cessation of business and loss of its provider agreement and number.

8. A CAH's Necessary Provider designation is associated with its current Medicare provider agreement that remains intact unless the CAH fundamentally changes its business (e.g., ceases its current operations) or is terminated by Medicare. It is a longstanding policy that the provider agreement describes the legal entity and services provided—not the physical structure or location.

On June 6, 2005, NRHA facilitated a conference call between a sample of CAH hospital CEOs, to provide specific examples of the impact this proposed regulation is having on their facilities. See **Attachment A** for a detailed account of their examples.

**Occupational Mix Adjustment**

CMS proposes to continue adjusting 10% of the wage index by an occupational mix adjustment. CMS noted last year some confusion and inconsistency with the data accumulated in the first occupational mix survey. We recognize this survey process was new to providers, intermediaries and CMS, and agree that there is likely a great deal of inconsistency in the way different hospitals completed the survey.

We encourage CMS to revisit this process immediately and gather new data within the next year, rather than waiting two more years before obtaining such data. At the same time, more detailed instructions should be issued to clarify the types of data reported, and how occupational data should be recorded on the survey form. CMS notes that a **Federal Register** notice will be published outlining changes to the survey process, and we look forward to reviewing this notice.

**Post acute Care Transfers**

CMS once again proposes to expand the post acute care transfer (PACT) policy. In describing the proposed expansion CMS notes that, of 507 active DRGs, 220 have lengths of stay of less than 3.0 days and 64 have fewer than 100 short-stay transfer cases. CMS proposes to include the remaining 223 DRGs under the PACT policy. Based on revised data posted to the CMS website, we understand there are now 231 DRGs proposed to be included under the PACT policy. We do not believe the proposed changes are in compliance with Section 1886(d)(5)(J) of the Act. This section requires that DRGs included under this policy must have "a disproportionate use of post discharge services."

While CMS notes that each of the selected DRGs had at least 2,000 PACT cases, CMS does not explain how this represents a "disproportionate use" of post discharge services. The plain meaning of the word "disproportionate" would indicate that, for a DRG to be included under the PACT policy, the usage of post discharge services would have to be outside the norm. CMS previously published criteria that somewhat accomplished this goal, by requiring 14,000 PACT cases for a DRG to be included under the policy. By excluding the 220 DRGs with lengths of stay of less than 3.0 days, CMS effectively proposes to include every other possible DRG under the policy that had 100 or more transfer cases.

To demonstrate that it has met the intent of the law, CMS should publish a complete list of all DRGs showing how many total cases each DRG had and how many of those cases included usage of post discharge services. The usage rate should also be computed for each DRG, as well as the overall average usage rate. We believe a usage rate at least one standard deviation above this average should be set as a minimum before a DRG is made subject to the PACT policy. We do not believe any change is needed in the current PACT policy. However, if CMS does propose such a change, we believe the clear intent of the law is to limit the PACT policy to DRGs with a disproportionate use of post discharge services, something CMS does not demonstrate with its proposal.

Further, we do not believe that CMS is required to implement changes to the PACT policy as actual reductions in Medicare spending. We request CMS make the postacute transfer policy a budget neutral policy, such that any reductions in Medicare spending through revisions to this policy be paid to providers through an increase in the PPS update factor.

**Sole Community Hospitals and Medicare Dependent Hospitals**

CMS proposes to modify the budget neutrality adjustment applied to hospital-specific payment rates for SCHs and MDHs to no longer consider changes in the wage index when applying the budget neutrality adjustment to hospital-specific payment rates. However, CMS fails to quantify the impact of this proposal. We request more detailed information regarding the impact of this change on fiscal 2006 payments, as well as the impact if this change was imposed retroactively.

**DSH Adjustment Data**

We appreciate the efforts CMS is making to comply with Section 951 of the Medicare Modernization Act, which required that CMS make certain DSH adjustment data available by December 8, 2004. CMS notes that a future **Federal Register** notice will publish more details on this issue. Due to the significance of this issue and the time that has already elapsed since December 8, 2004, we request that CMS expedite its efforts to make such data available.

**Geographic Reclassifications**

CMS proposes to update 42 CFR 412.103(a)(1) to use Rural-Urban Commuting Area codes to identify hospitals located in rural census tracts. However, it was difficult to locate these codes by going to the website identified in the proposed regulations. We request further clarification concerning these codes or a more detailed website reference to link to the codes.

Rural Hospitals Redesignated as Urban

As a result of the most recent labor market changes, some counties that were previously considered rural were redisignated as urban. Per the MMA, a rural county that is adjacent to one or more urban counties is considered to be located in the urban MSA to which the greatest number of workers in the county commutes, if certain conditions are met. These are known as"Lugar Counties." Thus, some CAHs are now located in Lugar counties and are unable to meet the rural location requirement, even through they were in full compliance at the time they were designated as critical access.

In response, CMS proposes that CAHs in counties that were designated Lugar counties effective October 1, 2004 because of the new labor market definitions will be allowed to maintain their CAH status until September 30, 2006. NRHA supports this continued transition to allow for the opportunity for these facilities to reclassify.

**Conclusion:**

We believe at this time, it is important to address for the public record, a much larger issue concerning CMS's internal misunderstanding of the CAH program in general.

Through CMS actions regarding the CAH program over the past four years, it appears that the agency internally perceives the growth of the CAH program incorrectly. **This growth of the CAH program was specifically intended by Congress. Furthermore, the growth of the program is limited by the number of rural hospitals that reasonable have twenty-five or fewer beds.** Every reasonable estimate puts this potential universe at less than 1500 hospitals nation-wide. Since more that 1100 hospitals have already converted to CAH status. That leaves less than 400 hospitals even potentially eligible for this designation. Attention should be paid to the total cost of the program (approximately $3B annually) and the additional cost as compared with all these CAHs being PPS hospitals (less than $800M according to MedPAC figures) compared with the total hospital budget this year for CMS of better than $239B. This makes the total CAH expenditure less than 0.01% of the total annual CMS hospital budget.

The NRHA appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Alan Morgan, Interim Executive Director at 703-519-7910 if you have any questions about these comments.

Sincerely,

Hilda Heady
President

# Congress of the United States
Washington, DC 20515

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CBSA
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June 23, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department for Health and Human Services
Attention: *CMS 1500-P*
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**RE: CMS-1500-P: MEDICARE PROGRAM; PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2006 RATES**

**COMMENTS RELATE TO FOLLOWING "ISSUE IDENTIFIERS":**
- **"REVISED MSAs" (Section III.B.)**
- **"HOSPITAL REDESIGNATIONS" (Section III.H.)**

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule with changes to the hospital inpatient prospective payment system (IPPS) and fiscal year 2006 rates published in the *Federal Register*. 70 Fed. Reg. 23305 (May 4, 2005). As referenced in Section III.B., FY 2006 will be the second year of the transition period provided in the FY 2005 IPPS final rule (69 Fed. Reg. 48916, August 11, 2004) for some hospitals that were previously classified as urban and are now in rural areas, based on new Metropolitan Statistical Areas (MSA) designations.

As legislators, we are extremely concerned about various aspects of CMS's FY 2005 and 2006 payment rules relating to the adoption of new geographic classifications regarding MSAs. We are writing to express our concern about nine hospitals across the United States that are suffering severe reductions in funding due to these changes. We respectfully request that CMS work to aid these hospitals, who by virtue of now being in a Micropolitan county, are reclassified as "Rural" despite their previous designation as a Metropolitan "Urban" hospital. We propose that this assistance be provided in the Medicare hospital inpatient prospective payment systems and fiscal year 2006 Rates Final Rule.

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The majority of the reduction in revenues is attributable to reductions in the Medicare disproportionate share hospital (DSH) adjustment, which is limited for rural hospitals. Urban hospitals of 100 or more beds have no cap on DSH payments. However, rural hospitals of all sizes are capped at 12% for DSH payments. The DSH adjustment provides an incentive for hospitals to provide healthcare services to Medicaid recipients.

In 2000, the Office of Management and Budget (OMB) established uniform criteria for defining MSA to describe the link between a large population concentration and the area surrounding it. According to the rules prior to the 2000 standardization, an area could be considered part of an existing MSA if 15% of the work force commuted to that MSA. In the 2000 rule, revisions were made to the definition of geographical statistical areas, and the qualifying percentage of the commuting work force was raised from 15% to 25%. CMS included this new definition in the FY 2005 IPPS Final Rule issued on August 11, 2004, and again in FY 2006 in the Proposed IPPS Rule issued on May 4, 2005.

OMB, in its new standards, established two categories of Core Based Statistical Areas (CBSAs): (1) Metropolitan Statistical Areas and (2) Micropolitan Statistical Areas. CMS' rule does not adopt the OMB definition of Micropolitan Statistical Areas for use in the payment system. Rather, Micropolitan Statistical Areas are proposed to remain part of the statewide rural area for purposes of inpatient prospective payment system payments.

However, OMB notes that the Metropolitan and Micropolitan Statistical Areas are solely for statistical purposes, stating that "***Metropolitan and Micropolitan Statistical Areas are not designated as a general geographic framework for nonstatistical activities or for use in program funding formulas. The CBSA classification does not equate to urban-rural classification ....***" 65 Fed. Reg. 82228, 82236 (Dec. 27, 2000). As such, we believe that CMS should be much more cautious in its use of OMB's standards for payment purposes, particularly when certain hospitals are adversely impacted.

We do not believe that CMS intended for the adoption of the new MSAs to severely harm hospitals. Therefore, we suggest that CMS consider the following options to ameliorate the harm that adoption of the new MSA definitions would cause:

We propose these nine hospitals be given the option to be reclassified from a Micropolitan rural classification to the Metropolitan urban classification as they were before the revision. Prior to 2000, these nine hospitals met the qualifying percentage for classification as Metropolitan urban hospitals. We understand under the 2000 standardization, however, these hospitals instead are treated as Micropolitan rural health hospitals with a reduction in DSH payments. We are concerned about the adverse impacts these changes would have on our hospitals. These nine hospitals would lose millions of dollars each year under the Micropolitan rural classification, with one hospital alone losing $2 million dollars per year.

These exceptions should apply to urban classification for both wage index and DSH adjustment purposes. Other policy options are possible. For example, CMS could adopt, as an alternative,

OMB's new definitions but allow a lower commuting threshold instead of a 25% threshold. We feel strongly that CMS should adopt a policy interpretation that would not harm hospitals, which would otherwise be adversely affected by the CMS proposed rule. This would result in a fair and equitable recognition of the proper classifications of hospitals.

CMS has already noted elsewhere in the proposed rule that it has sufficient authority to provide exceptions. As Section 1886(d)(5)(I)(i) of the Social Security Act notes, the "Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." *See* 70 Fed. Reg. at 23433.

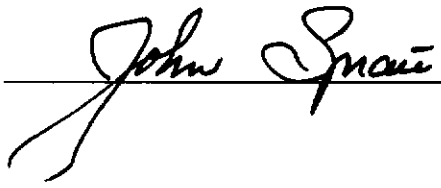
We respectfully request that an exception be made, as described above, for the nine hospitals we represent.

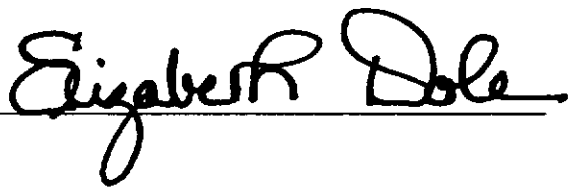
We thank you in advance for your prompt attention to this matter. We look forward to hearing from you.

Sincerely,

David Vitter
U.S. Senator

Charles Boustany
Member of Congress





Hospitals that will be negatively impacted by the new Metropolitan Statistical Areas designations

American Legion Hospital
Crowley, LA 70526
Provider # 190044

Doctors Hospital of Opelousas
Opelousas, LA
Provider # 190191

Integris Bass Baptist Health Center
Enid, OK
Provider # 370016

Minden Medical Center
Minden, LA
Provider # 190144

Pattie A. Clay Hospital
Richmond, KY
Provider # 180049

Community Health Centers, Inc.
Unity Health Center
Shawnee, OK 74804
Provider # 370149

St. Mary's Hospital at Amsterdam
Amsterdam, NY
Provider # 330047

Thomasville Medical Center
Thomasville, NC
Provider # 340085

Upstate Carolina Medical Center
Gaffney, SC
Provider # 420043

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AstraZeneca

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JUN 28 2005

**Stephen D. McMillan**
Director Government Reimbursement
Federal Government Affairs

Tel 202 350 5577
Fax 202 350 5510

DRG/Gen (Strokes)

Hefter.
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 24, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, 70 Fed. Reg. 85, 23306 (May 4, 2005) [File Code: CMS-1500-P]**

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit comments on the proposed rule issued by the Centers for Medicare & Medicaid Services ("CMS") to implement Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates (the "Proposed Rule"), 70 Fed. Reg. 85, 23306 (May 4, 2005). We appreciate this opportunity to share our views on the important changes proposed to the DRG structure for stroke care.

Stroke and its long-term consequences are significant public health issues, and are of particular import for the Medicare program. On average, every 45 seconds someone in the United States has a stroke, which equates to nearly 700,000 new or recurrent events each year. Stroke is a leading cause of serious, long-term disability and ranks third in all causes of death behind heart disease and cancer.[1] In 2005 the estimated direct cost of stroke is $35 billion, with nearly $15 billion in hospital services alone.[2] Congress has recognized stroke as a public health issue and there exist bills in both the Senate and the House of Representatives to address stroke through more robust early identification activities and interventions as well as preventive measures.[3] In general, stroke care has traditionally been in the form of active palliation, with a focus on stabilizing the patient and then following quickly with an aggressive rehabilitation program. While these efforts are necessary, there is a trend toward more aggressive treatment of the acute event. Reperfusion agents and a number of new pharmacological and procedural interventions are currently in development, with the common aim of minimizing the damage to brain tissue from the ischemic event.

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1 American Stroke Association, *Heart Disease and Stroke Statistics – 2005 Update*, pp. 16-18.

2 American Stroke Association, *Heart Disease and Stroke Statistics – 2005 Update*, p. 53.

3 Stroke Treatment and Ongoing Prevention Act, S.1064. and H.R.898.

AstraZeneca is one of the world's leading pharmaceutical companies, engaged in the research and development of new medicines. Through its leadership in the cardiovascular, oncology, neuroscience, gastrointestinal, and respiratory areas, AstraZeneca is committed to the discovery of drugs that will allow Medicare beneficiaries to lead longer, healthier, and more productive lives. In keeping with this commitment, AstraZeneca has a long-standing drug development program targeted at effective therapies for stroke, and presently is conducting Phase III trials of a stroke drug candidate which, if approved, will be subject to the payments provided to hospitals under the Inpatient Prospective Payment Systems (IPPS). As such, AstraZeneca applauds CMS's consideration of the adequacy of payment for stroke cases.

AstraZeneca understands that several hospital stroke centers have proposed using tissue plasminogen activator (tPA) as a proxy to identify patients with severe strokes. Representatives of these centers have stated that these tPA cases generate higher charges than other stroke cases because of the higher hospital resource utilization they entail. CMS performed an analysis of Medicare stroke case charges, and has found that the average standardized charges for cases treated with tPA are more than $16,000 and $10,000 higher than those of all other cases in DRGs 14 and 15, respectively.[4] The hospital stroke centers offered two alternatives for rearranging the stroke DRGs. The first would group ischemic reperfusion cases in a renamed DRG 14, with all other ischemic and hemorrhagic cases grouped into DRG 15. The second would leave DRGs 14 and 15 as they currently exist, and group ischemic reperfusion cases in a new DRG. AstraZeneca further understands that CMS is not proposing any changes to the stroke DRGs at this time, because the charge differential is based on a small number of reported tPA stroke interventions.

The following comments address a number of specific considerations raised by the suggested changes in the Proposed Rule. We are available to provide additional information about any of these items or answer any questions you may have.

**Summary of AstraZeneca's Position on the Proposed Stroke DRG Change**

First, AstraZeneca supports in general any changes to the DRG system that would facilitate beneficiary access to improved stroke care, by enabling more rapid diffusion of worthy treatments and hospital reimbursement for stroke cases that is more commensurate with their costs. As such, we believe that the stroke centers' proposal is worthy of serious consideration by CMS.

However, AstraZeneca believes that the proposed stroke DRG changes are too limited as written. The proposed descriptor, "reperfusion agent", is not broad enough to encompass other promising pharmacotherapies for stroke that are in late stages of clinical development. These novel therapies include GP IIb/IIIa inhibitors and neuroprotectants for ischemic stroke, and recombinant Factor VIIa for hemorrhagic stroke. By broadening the title for the proposed new DRG to include a wider range of acute pharmacotherapies, CMS could accelerate more appropriate payment for stroke cases including any such newly approved therapies. In contrast, implementing the proposed narrowly-defined change would require further modification of the stroke DRGs, potentially in the near future, to facilitate full

[4] 70 Fed. Reg. 85, 23316 (May 4, 2005).

beneficiary access by ensuring adequate reimbursement to the institutions that may use these therapies if approved.

AstraZeneca believes that creating a new, broader DRG for stroke pharmacotherapy is an appropriate step for three reasons. First, the development of these pharmacotherapies for acute stroke treatment signals a paradigm shift in stroke management, not dissimilar to the paradigm shift in heart attack management decades ago. It reflects an emerging medical understanding of the pathophysiological process of the stroke itself and represents a shift of care from active palliation of symptoms to aggressive intervention to minimize or avoid functional losses. As such, all of these pharmacotherapies exhibit a clinical coherence that is greater among them, than between each therapy and the remainder of stroke cases. They, like reperfusion agents, are intended to actively treat the acute event in order to change the natural course of the damage being inflicted on the brain tissue. Second, while the actual case expenses for each of these developing therapeutic options are not presently known, cases involving any of these agents might be expected to be relatively costly. Similar to the situation for tPA, the increased costs of these cases are likely to be quite different from those strokes involving only active palliation. Third, while CMS has expressed concern that there may be insufficient thrombolytic cases to justify the proposed change in stroke DRGs, enabling the future addition of these emerging technologies could effectively broaden the treatable case population in the new DRG considerably. Thus, a new, broader DRG for stroke pharmacotherapy likely would meet CMS's DRG criteria of clinical coherence among cases, internal charge coherence with a significant difference from other, related DRGs, and a sufficient number of cases to warrant separation in a different DRG.

Therefore, AstraZeneca endorses either of the suggested stroke DRG rearrangements, provided that the title of the proposed DRG for reperfusion cases was changed to the following: "Ischemic or Hemorrhagic Stroke Treatment with Acute Pharmacologic Intervention."

**Limitations of the Stroke DRG Change Proposal Would be Addressed by Broadening the Title**

The current proposal, while admirable in its attempt to ensure clinically-appropriate access to tPA therapy for stroke, nevertheless has a number of significant shortcomings:

- Because only a minority of stroke cases is eligible for treatment with tPA, the proposed change would improve access to therapy for only a small fraction of all stroke patients.

- Because only a single type of reperfusion agent is presently approved for stroke treatment, the proposed change would create a DRG that is, *de facto*, product specific.

- The proposed change addresses case charge disparities associated with the use of a particular therapeutic option, but fails to address the clinical coherence intrinsic to the variety of emerging pharmacotherapeutic options for stroke treatment currently under development.

- Implementing such a narrowly-defined change may necessitate further changes to the stroke DRGs in the near future to ensure patient access to emerging drug therapies once approved.

In contrast, implementing the stroke DRG change proposal with a broader title would address these shortcomings:

- Allowing for additional acute pharmacologic interventions to be added to the "reperfusion" DRG would, by definition, increase the number of patients for which the new DRG would enhance access to appropriate stroke therapy. Although the group of patients receiving tPA therapy may, by itself, be too small to justify realigning the stroke DRGs, this group plus those potentially receiving GP IIb/IIIa inhibitors, clotting factors, or neuroprotectants likely would constitute a "critical mass".

- Broadening the title of the proposed "reperfusion" DRG would, by definition, make the new DRG not product specific.

- Broadening the title of the proposed DRG to encompass a variety of pharmacotherapies would acknowledge the intrinsic clinical coherence of acute pharmacologic intervention cases. Before the approval of tPA for stroke, all strokes were managed similarly, regardless of type (ischemic vs. hemorrhagic) – first by stabilizing the patient, and then by initiating a rehabilitation program as soon as feasible. Thus, because virtually all strokes were managed in a similar fashion, the primary driver of clinical coherence was the etiology of the stroke. The emergence first of tPA (FDA-approved indication in 1996), and then of several other potential therapeutic options (currently in clinical investigations to document safety and efficacy), for treatment of stroke represents a paradigm shift in the clinical approach to these cases. Under this new paradigm of aggressive intervention, the primary driver of clinical coherence among stroke cases has changed from etiology to the type of case management – interventional vs. palliative.

- Implementing a more broadly defined stroke DRG change at present would allow CMS to efficiently accommodate future, deserving pharmacotherapies without subsequent DRG changes. Moreover, to include other pharmacotherapies, CMS would only need to map the ICD-9-CM procedure codes for their administration to the DRG. Because CMS retains complete control over i) the creation of ICD-9-CM procedure codes, ii) their mapping to the newly defined DRG, and iii) the definition (through Coding Clinic) of how each code may be used, there is essentially no risk of upcoding or inappropriate mapping of cases to the DRG. In fact, ICD-9-CM codes already exist for thrombolytic administration (99.10), GP IIb/IIIa inhibitor administration (99.20), and neuroprotectant administration (99.75). There are relatively few other infused agents currently identified by a specific ICD-9-CM procedure code.

**Additional Benefits that Could Accrue From a Broader DRG Title**

Medicare beneficiaries and CMS would experience additional benefits from the facilitation of more appropriate reimbursement for a wider range of drug treatments for stroke.

- More appropriate reimbursement for effective pharmacotherapies may lead to significant cost offsets in subsequent healthcare utilization for stroke patients. Medicare incurs significant costs for skilled nursing, rehabilitation, and clinical management of stroke sequelae. Acute pharmacologic interventions in development offer the promise of reducing the impact of these downstream cost drivers.

- More appropriate reimbursement for acute pharmacologic interventions will improve the hospitals' ability to maintain adequate stocking levels of these agents and thereby facilitate patient and physician access in the acute timeframe necessary for their use.

- Private payers that use DRG-based or similar case-rate hospital prospective payment systems often look to CMS for guidance in the structure of their systems. By taking the lead in providing more appropriate DRG-based reimbursement for effective stroke pharmacotherapies, CMS could influence similarly appropriate payment by private payers. Such leadership by CMS could have the effect of reducing the number of younger stroke victims entering the Medicare program because of their disability.

**A Broader DRG Title is Timely and Appropriate**

In addition to tPA, which is already approved and marketed for stroke treatment, multiple other pharmacologic options that may be suitable for a broad range of patients may be nearing clinical use. Such options include, but are not limited to, the following:

- Hemorrhagic stroke – recombinant Factor VIIa: NovoSeven® is routinely used in the United States for the treatment of spontaneous and surgical bleedings in hemophilia A and B patients with antibodies (inhibitors) against factors VIII (FVIII) and IX (FIX), respectively. A recently completed Phase 2b dose-ranging study demonstrated that treatment with recombinant Factor VIIa resulted in less hematoma volume growth, a reduction in the number of patients with moderately severe disability, and a reduction in mortality at day 90.[5]

- Ischemic stroke – GP IIb/IIIa inhibitors: Reopro®, which is approved for cardiological uses, has shown promising results in a Phase IIb trial for up to six hours after symptom onset.[6] A larger, 1,500-patient Phase III trial is now underway.

- Ischemic stroke– neuroprotectants: NXY-059, an investigational compound proposed to work by free-radical trapping, in a first analysis of data from one of the two Phase IIb/III SAINT trials involving more than 1700 patients, showed a reduction versus placebo on the primary outcome of disability after an acute ischemic stroke (p= 0.038), as measured by the Modified Rankin Scale.[7]

While additional research is underway to truly define the role of these potential therapies, it is likely that none of them are expected to be approved for use in stroke during Medicare's FY 2006. Nevertheless, all are progressing steadily through clinical trials for acute stroke, and two have been previously approved for other indications. Thus, CMS has a rare opportunity to take an action in advance that will prepare the agency to facilitate beneficiary access if and when these drugs are approved, without any material risk on the agency's part.

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[5] Mayer SA, Brun NC, Begtrup K, et al. Recombinant activated factor VII for acute intracerebral hemorrhage. N Engl J Med 2005; 352:777-85.

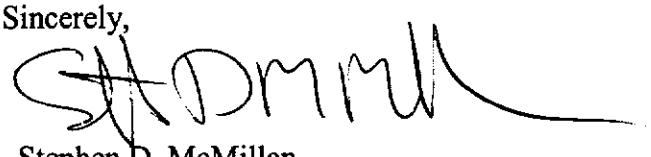
[6] AbESTT Investigators: Effects of Abciximab for Acute Ischemic Stroke: Final Results of Abciximab in Emergent Stroke Treatment Trial (AbESTT). Stroke 2003; 34: 253.

[7] Data on file, AstraZeneca; Presentation of SAINT I results, European Stroke Conference, Bologna, Italy, May 28, 2005

* * * * *

Again, AstraZeneca appreciates the opportunity to comment on the Proposed Rule. We look forward to working with CMS to promote high-quality stroke care for Medicare beneficiaries. Please do not hesitate to contact me at (202) 350-5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,



Stephen D. McMillan
Director, Government Reimbursement

Cc: Marc Hartstein

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AdvaMed
Advanced Medical Technology Association

MB/H

Hefter
Hartstein
Seifert
Knight

June 24, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: CMS-1500-P
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

Dear Dr. McClellan:

On behalf of the nation's blood centers, hospital blood banks and transfusion services, manufacturers of blood-related medical technologies, and professionals involved in all aspects of blood collection and transfusion medicine, we are writing to comment on the treatment of blood and blood components under the Centers for Medicare and Medicaid Services (CMS) proposed rule updating the Medicare hospital inpatient prospective payment system (PPS) for fiscal year 2006.

Our organizations are concerned about CMS' proposal to eliminate blood and blood products as a separate category in the Market Basket and add it to the "Miscellaneous Products" cost category. We are also concerned about the proposal to use the Producer Price Index (PPI) for finished goods less food and energy as the price proxy for this category.

As noted in the preamble to the proposed rule, in the FY 1997-based market basket, CMS included a separate cost category for blood and blood products. This action was consistent with a MEDPAC Report to Congress[1] titled, "Blood Safety in Hospitals and Medicare Inpatient Payment," (December 2001), that contained the following key recommendation:

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1 The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2002 (BIPA), Congress required CMS to determine whether the price of blood products was adequately reflected in the market basket. That same legislation also ordered the Medicare Payment Advisory Committee (MedPAC) to provide this study and to address, inter alia, the treatment of blood and blood products in Medicare's inpatient prospective payment system.
CMS to give special attention to the adequacy of payment for blood and blood products when revising the market basket

**When CMS revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.**[2]

As noted in the MEDPAC Report, blood and blood products were included as a separate cost category in the Market Basket prior to fiscal year 1997. The category was combined with the chemicals component beginning in fiscal year 1997 but was listed as a separate category again beginning in fiscal year 2003.

The Report notes that the CMS decision to add blood and blood products to the chemicals component was motivated by "a lack of appropriate data for calculating a weight for blood services." This reason no longer exists since not only was the agency able to calculate a weight for the 2003 market basket (0.875) but also lists the weight in the current proposed rule (1.082). In fact, it appears that the only reason for eliminating the separate category for blood and blood products was to enable the agency to add it to a category for which a proxy unrelated to blood either conceptually or with regard to actual data trends could be applied. We urge CMS to act in accordance with the MEDPAC Report recommendation and retain blood and blood and blood products as a separate cost category in the Market Basket.

We appreciate CMS's review of three alternative price proxies for blood and blood products. As noted in the proposed rule, CMS previously used the Bureau of Labor Statistics (BLS) PPI (commodity code #063711) for blood and derivatives as a price proxy. We agree that price movements in the major component of the PPI for blood and derivatives recently were not consistent with trends in blood costs for all the products used by hospitals for inpatient care. However, we know of no data indicating that the PPI for finished goods, less food and energy, has "moved most like the recent blood cost and price trends," as CMS states. The agency goes on to say that it believes that this index will "best be able to proxy price changes (not quantities or required tests) associated with blood purchased by hospitals." However, CMS provides no support for why it believes that to be true.

We ask you to provide the public, in particular the blood banking community, with the data upon which CMS is making this judgment that blood costs most closely track finished goods costs. Absent disclosure and public discourse of convincing data, we believe that blood should not be moved temporarily to yet another unrelated category to which an unrelated PPI is being applied. Rather, whatever steps possible should be taken to expedite the establishment of a new blood-related PPI that accurately tracks changes in blood costs that hospitals purchased for inpatient care. The BLS has begun work in creating this new PPI and we look forward to continuing to work with BLS and CMS on this initiative.

On a related matter, we seek clarification from CMS regarding what is meant by excluding "quantities or required tests" from changes in blood costs. In any measure of

2 Medicare Payment Advisory Commission, Report to the Congress, "Blood Safety in Hospitals and Medicare Inpatient Payment," p. 14

price changes for blood, costs associated with ongoing blood testing and processing should be included as price changes in the PPI, since these procedures are required either by federal regulation, voluntary accrediting agencies or as standard of care to protect the public's health and safety and to ensure that the all blood collected in the country meets the same safety standards. As new and emerging diseases and conditions affect the nation's blood supply, additional testing or processing will be necessary to maintain the safest possible blood. Thus, tracking the price of a *safe* unit of blood over time should be CMS's goal, rather than developing a portfolio of blood products that reflects the costs of providing safe blood at only one point in time historically. Moreover, hospitals and other facilities that purchase blood products typically have no option but to purchase these products subject to testing and processing requirements. These blood product testing and processing requirements maintain the standard of care in the blood collection industry. There are no other products that could substitute for these blood products.

We appreciate CMS' careful consideration of the complex issues involving inpatient reimbursement for blood and blood products. If you have any questions or require additional information, please contact Theresa L. Wiegmann, AABB director of public policy, at 301-215-6554 or Theresa_L@aabb.org.

Sincerely,

AABB
America's Blood Centers
American Red Cross
Advanced Medical Technology Association (AdvaMed)

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June 24, 2005

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**VIA HAND DELIVERY**

novo nordisk®

Mark McClellan, MD, PhD
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BCF
DRG
NT

Hefler
Hartstein
Gruber
Brooks
FASAR
Kelly
Hue
Walz
Treitel

Re: File Code CMS-1500-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule

Dear Administrator McClellan:

Novo Nordisk appreciates the opportunity to submit these comments regarding the Inpatient Prospective Payment System Proposed Rule for Fiscal Year 2006 (Proposed Rule). Novo Nordisk is a healthcare company, a world leader in diabetes care, and the manufacturer of NovoSeven®. The company has the broadest diabetes product portfolio in the industry and a leading position within areas such as hemostasis management. We develop, manufacture, and market pharmaceutical products and services that make a significant difference to patients, the medical profession, and society. NovoSeven® is a recombinant Factor VIIa product that does not replace Factors VIII or IX, but enables coagulation to proceed in their absence. NovoSeven® can therefore be used by people who have developed a resistance to these factors.

Novo Nordisk wishes to comment on two sections of the proposed rule: Blood Clotting Factor Payment and Diagnosis Related Group Reclassification.

**Blood Clotting Factor Payment**

Currently, Medicare reimburses hospitals at 95 percent of the average wholesale price (AWP) for blood clotting factors administered to hospital inpatients with hemophilia. In FY 2006, CMS proposes to establish a payment methodology for clotting factors in this setting consistent with payment for Medicare Part B drugs not paid on a cost or prospective basis. The proposed rule contains the following language:[1]

*"For this reason, we are proposing for FY 2006 that the fiscal intermediaries make payment for blood clotting factor using 106 percent of the [average sales price] and make payment for the furnishing fee at $0.14 per individual unit (IU) that is currently used under Medicare Part B."*

[1] 70 Fed. Reg. 23482, (May 4, 2005).

Novo Nordisk
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Novo Nordisk supports CMS' proposal to pay for clotting factors consistently under Medicare Parts A and B in FY 2006. We would like to point out, however, that clotting factors are described in terms of International Units (IUs). NovoSeven®, Coagulation Factor VIIa (Recombinant), which is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factors VIII or IX, is dosed in micrograms rather than IUs. Moreover, CMS has established under Part B that, for the purpose of providing the $0.14 per unit furnishing fee, a single unit of NovoSeven® is equal to one microgram.

In order to ensure consistency between Parts A and B, Novo Nordisk urges CMS to designate one microgram as one unit for the purpose of payment under the ASP methodology and for providing the furnishing fee to hospital inpatient providers. In order to circumvent any confusion regarding the definition of units of NovoSeven® (which occurred following the release of the 2005 Medicare Physician Fee Schedule Final Rule), Novo Nordisk also asks that CMS clearly state in the preamble and regulatory text of the 2006 Hospital Inpatient Prospective Payment System Final Rule that one microgram of NovoSeven® is equal to one unit for the purpose of providing the $0.14 per unit furnishing fee.

We also request that CMS assure that its claims processing systems are modified and tested prior to implementation of this change in payment methodology to minimize claims processing problems and improper payments under the new methodology.

**Diagnosis Related Group (DRG) Reclassifications**

In its proposed rule CMS discusses, but does not propose, two suggested modifications to DRG 14 (Intracranial Hemorrhage or Cerebral Infarction) and DRG 15 (Nonspecific CVA and Precerebral Occlusion Without Infarction) and invites comments on those suggestions.

- The first suggestion would modify DRG 14 by having it include only stroke cases where a reperfusion agent was administered, as defined by the presence of International Clinical Diagnosis, 9th Revision, Clinical Modification (ICD-9-CM) code 99.10, *Injection or infusion of thrombolytic agent*, on the claim. DRG 15 would then be modified to include all stroke cases (hemorrhagic and non-hemorrhagic) where a reperfusion agent was not administered.

- The second suggestion would remove all cases where a reperfusion agent was administered, as defined by the presence of ICD-9-CM code 99.10 on the claim, from DRGs 14 and 15 and place them in a new DRG which would contain only ischemic stroke cases where a reperfusion agent was administered. The basis for these suggestions is that cases involving the administration of reperfusion agents have higher costs than those that do not involve use of those agents.[2]

[2] CMS also states that use of reperfusion agents may be a proxy for the severity of the stroke but does not present or discuss clinical data supporting this concept.

The CMS analysis of its hospital claims data shows that cases in DRG 14 involving the use of reperfusion agents had average standardized charges that were $16,000 greater than charges for cases not involving administration of reperfusion agents. However, CMS did not propose to modify the DRG because of the small number of claims where ICD-9-CM code 99.10 appeared (i.e., 2,085 out of 180,373 non-hemorrhagic stroke cases and 61 out of 41,506 hemorrhagic stroke cases). Therefore, CMS did not propose payment rates for any DRGs that would be created under either suggestion.

Novo Nordisk is concerned that implementation of either suggestion discussed in the proposed rule will adversely affect patient access to important emerging treatments for stroke, such as the use of NovoSeven® for treatment of intracerebral hemorrhage (ICD-9-CM code 431, which is assigned to DRG 14), because such cases would be inadequately reimbursed under the suggested DRG structure.

Intracerebral hemorrhage affects 105,000 patients per year in the United States, has a 40 percent one month mortality rate, and two-thirds of survivors never regain functional independence.[3] Because there is no effective treatment for intracerebral hemorrhage, care has been purely supportive. A recent randomized placebo controlled clinical trial using NovoSeven® to treat patients with intracerebral hemorrhage showed that when NovoSeven® was administered within four hours of symptom onset, there was significant decrease in the size of the bleed which resulted in a combined mortality and severe disability rate of 50 percent at 90 days.[4,5] Additional studies are ongoing, and Novo Nordisk hopes that NovoSeven® will receive an indication for use in intracerebral hemorrhage from the Food and Drug Administration (FDA) in 2007. Due to the lack of treatment options for intracerebral hemorrhage, many physicians may begin using NovoSeven® for this indication.

Insufficient reimbursement of NovoSeven® may pose a significant economic burden to hospitals. For example, based on the Average Sales Price (ASP) of $0.83,[6] the cost of a single, standard dose of 80mcg/kg of NovoSeven® for a 70 kg patient would cost $4,648.00. This cost, while less than the entire DRG payment of $5,793.50, will reduce or eliminate hospitals' margins and increase the likelihood that hospitals will experience a significant financial loss on all cases where NovoSeven® is used.

In order to ensure patient access to emerging technologies for the treatment of stroke such as NovoSeven®, Novo Nordisk urges CMS to modify DRGs 14 and 15 in a manner that

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[3] Broderick, J.P., et al. 1999. Guidelines for the management of spontaneous intracerebral hemorrhage. *Stroke, 30,* 905-915.

[4] The reduction in mortality alone was 38 percent at 90 days.

[5] Mayer, S.A., et al., 2005. Recombinant Activated Factor VII for acute intracerebral hemorrhage. *N Engl J Med 2005;*352:777-85 (Enclosure).

[6] April 2005 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File CR 3846, Pub. 100-04, Rev. 561 – May 13, 2005). Accessed June 20, 2005, http://www.cms.hhs.gov/providers/drugs/asp.asp. CMS payment amount of 106 percent of ASP for NovoSeven® is listed as $1,228.438 for a 1.2mg vial; cost was calculated based on ASP minus $0.14 furnishing fee per I.U., which equals $0.83/mcg.

accounts for the cost of such technologies. With this in mind, Novo Nordisk makes the following recommendations:

**Recommendation 1:**
**Novo Nordisk Preferred Options for Modifying DRGs 14 and 15**

Novo Nordisk encourages CMS to modify DRGs 14 and 15 using one of the following options:

**Option 1**

Modify DRGs 14 and 15 into two DRGs as follows (see Figure 1): DRG A would contain hemorrhagic and ischemic stroke cases where only supportive care was given without additional pharmacological intervention, and DRG B would contain hemorrhagic and ischemic stroke cases in which reperfusion or hemostatic agents were administered.

**Figure 1**

| DRG A |
| --- |
| Hemorrhagic & Ischemic Stroke Cases, Given Supportive Care Only |

| DRG B |
| --- |
| Hemorrhagic & Ischemic Stroke Cases, Given Reperfusion or Hemostatic Agents |

**Option 2**

Modify DRGs 14 and 15 by creating four new DRGs based on stroke type and treatment (see Figure 2). DRG A would include hemorrhagic stroke cases where only supportive care was given. DRG B would contain hemorrhagic stroke cases where hemostatic agents were administered. DRG C would contain ischemic stroke cases where only supportive care was given. DRG D would contain ischemic stroke cases where reperfusion agents were administered.

**Figure 2**

| DRG A |
| --- |
| Hemorrhagic Stroke Cases, Given Supportive Care Only |

| DRG B |
| --- |
| Hemorrhagic Stroke Cases, Given Hemostatic Agents |

| DRG C |
| --- |
| Ischemic Stroke Cases, Given Supportive Care Only |

| DRG D |
| --- |
| Ischemic Stroke Cases, Given Reperfusion Agents |

Both options assure increased reimbursement for cases involving reperfusion therapy as well as for cases involving emerging technologies such as NovoSeven®. Moreover, both options also provide CMS the ability to include future treatment innovations in the "reperfusion/hemostatic agent" DRG without requiring CMS to create additional or modify existing DRGs.

**Recommendation 2:**
**Examine Intracerebral Hemorrhage Cases as a Way to Reconfigure DRGs 14 and 15**

Should CMS not adopt Recommendation 1 and decide to modify DRGs 14 and 15 without taking into account hemostatic therapies such as NovoSeven®, Novo Nordisk urges CMS, prior to implementing such a change, to review the costs of intracerebral hemorrhage cases. This would enable CMS to determine whether those cases have higher costs than other stroke cases and therefore should be placed in a separate DRG.

**Recommendation 3**
**Minimize Underpayment for Stroke Cases Not Involving Reperfusion Agents**

Should CMS not adopt Recommendation 1 and decide to modify DRGs 14 and 15 to increase reimbursement for cases involving the use of reperfusion agents without taking into account hemostatic therapy such as NovoSeven®, we urge CMS to implement its decision in a way that minimizes any decrease in payment for stroke cases not involving the use of reperfusion agents. Moreover, if CMS modifies DRGs 14 and 15 without taking hemostatic therapy into account, Novo Nordisk encourages CMS to state explicitly in the final rule that it will continue to review DRG 14 in order to identify other groups of clinically coherent, high cost cases that might be used to further modify DRGs 14 and 15 and to assure appropriate reimbursement for emerging technologies in the treatment of stroke.

**Recommendation 4: Tracking Cost and Utilization of Hemostatic Agents**

Due to the likelihood of increasing use of NovoSeven® for the treatment of intracerberal hemorrhage, Novo Nordisk believes it is important to begin accurate and immediate tracking of the use and cost of hemostatic agents in stroke cases. Therefore, Novo Nordisk urges CMS to state in the preamble of the final rule that hospitals should use ICD-9-CM code 99.06, *Transfusion of coagulation factors,* when products such as NovoSeven® are used for the treatment of hemorrhagic stroke. CMS should also state that administration of products such as fresh frozen plasma and cryoprecipitate, which have multiple uses in critically ill patients (e.g., expansion of plasma volume), should be coded under ICD-9-CM code 99.07, *Transfusion of other serum.*

In summary, Novo Nordisk urges CMS to modify DRGs 14 and 15 in such a way that the costs of emerging technologies such as NovoSeven® are considered and to instruct hospitals to use ICD-9-CM code 99.06 for reporting the use of hemostatic agents such as NovoSeven® in order to collect accurate utilization and cost data. If CMS decides not to take such technologies into account and alters DRGs 14 and 15 in accordance with one of the two suggestions discussed in the Proposed Rule, Novo Nordisk suggests the agency do so in a way that minimizes any decrease in reimbursement for stroke cases not involving the use of reperfusion agents. Novo Nordisk also recommends that CMS explicitly state in the final rule that the agency is committed to ongoing review of DRG 14 to assure that emerging technologies for the treatment of stroke are reimbursed

appropriately.

We appreciate the opportunity to submit these comments on the Proposed Rule for the Hospital Inpatient Prospective Payment System and would be happy to answer any questions you may have. Please contact me at (202) 663-7851.

Sincerely,

Michael Mawby/cm

Michael Mawby
Chief Government Affairs Officer
Novo Nordisk

Enclosure

ORIGINAL ARTICLE

# Recombinant Activated Factor VII for Acute Intracerebral Hemorrhage

Stephan A. Mayer, M.D., Nikolai C. Brun, M.D., Ph.D., Kamilla Begtrup, M.Sc., Joseph Broderick, M.D., Stephen Davis, M.D., Michael N. Diringer, M.D., Brett E. Skolnick, Ph.D., and Thorsten Steiner, M.D., for the Recombinant Activated Factor VII Intracerebral Hemorrhage Trial Investigators*

## ABSTRACT

### BACKGROUND

Intracerebral hemorrhage is the least treatable form of stroke and is associated with high mortality. Among patients who undergo computed tomography (CT) within three hours after the onset of intracerebral hemorrhage, one third have an increase in the volume of the hematoma related to subsequent bleeding. We sought to determine whether recombinant activated factor VII (rFVIIa) can reduce hematoma growth after intracerebral hemorrhage.

### METHODS

We randomly assigned 399 patients with intracerebral hemorrhage diagnosed by CT within three hours after onset to receive placebo (96 patients) or 40 μg of rFVIIa per kilogram of body weight (108 patients), 80 μg per kilogram (92 patients), or 160 μg per kilogram (103 patients) within one hour after the baseline scan. The primary outcome measure was the percent change in the volume of the intracerebral hemorrhage at 24 hours. Clinical outcomes were assessed at 90 days.

### RESULTS

Hematoma volume increased more in the placebo group than in the rFVIIa groups. The mean increase was 29 percent in the placebo group, as compared with 16 percent, 14 percent, and 11 percent in the groups given 40 μg, 80 μg, and 160 μg of rFVIIa per kilogram, respectively (P=0.01 for the comparison of the three rFVIIa groups with the placebo group). Growth in the volume of intracerebral hemorrhage was reduced by 3.3 ml, 4.5 ml, and 5.8 ml in the three treatment groups, as compared with that in the placebo group (P=0.01). Sixty-nine percent of placebo-treated patients died or were severely disabled (as defined by a modified Rankin Scale score of 4 to 6), as compared with 55 percent, 49 percent, and 54 percent of the patients who were given 40, 80, and 160 μg of rFVIIa, respectively (P=0.004 for the comparison of the three rFVIIa groups with the placebo group). Mortality at 90 days was 29 percent for patients who received placebo, as compared with 18 percent in the three rFVIIa groups combined (P=0.02). Serious thromboembolic adverse events, mainly myocardial or cerebral infarction, occurred in 7 percent of rFVIIa-treated patients, as compared with 2 percent of those given placebo (P=0.12).

### CONCLUSIONS

Treatment with rFVIIa within four hours after the onset of intracerebral hemorrhage limits the growth of the hematoma, reduces mortality, and improves functional outcomes at 90 days, despite a small increase in the frequency of thromboembolic adverse events.

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*The participating institutions and investigators are listed in the Appendix.

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INTRACEREBRAL HEMORRHAGE IS ONE OF the most disabling forms of stroke. More than one third of patients with this disorder die within one month after the onset of symptoms, and only 20 percent regain functional independence.[1] There is currently no effective treatment for intracerebral hemorrhage.[2]

The volume of the hematoma is a critical determinant of mortality and functional outcome after intracerebral hemorrhage,[3,4] and early hematoma growth is an important cause of neurologic deterioration.[5-8] An increase in volume of more than 33 percent is detectable on repeated computed tomography (CT) in 38 percent of patients initially scanned within three hours after onset; in two thirds of cases with growth in volume, this increase is evident within one hour.[5] Early hematoma growth occurs in the absence of coagulopathy and appears to result from continued bleeding or rebleeding at multiple sites within the first few hours after onset.[9]

Intervention with so-called ultra-early hemostatic therapy in the emergency department might improve outcomes after intracerebral hemorrhage by arresting ongoing bleeding and minimizing increases in the volume of the hematoma.[9] Recombinant activated factor VII (rFVIIa) is approved to treat bleeding in patients with hemophilia who have antibodies to factor VIII or IX, and it has been reported to reduce bleeding in patients without coagulopathy as well.[10] In two recent dose-escalation safety studies, we found that doses of rFVIIa ranging from 5 to 160 μg per kilogram of body weight were not associated with a high frequency of thromboembolic complications in patients with acute intracerebral hemorrhage.[11,12] We conducted the present trial to determine whether rFVIIa can effectively reduce hematoma growth in patients with acute intracerebral hemorrhage, and thus improve their outcomes.

## METHODS

### STUDY DESIGN

Patients were enrolled in this double-blind, placebo-controlled trial from August 2002 through March 2004 at 73 hospitals in 20 countries (see the Appendix). The trial was approved by local institutional review boards and by local and national ethics boards as applicable. Informed consent was obtained from the patient or a legally acceptable surrogate. In some instances, if the patient lacked the capacity to give consent, the requirement for consent was waived in accordance with local and national regulations. The authors wrote the trial protocol and the manuscript, whereas the sponsor was responsible for collecting the data (data collection was performed by Quintiles Transnational, a contract research organization). The authors had full access to the data, directed the data analysis, and were responsible for decisions regarding publication. The principal investigator (Dr. Mayer) assumes full responsibility for the integrity and interpretation of the data.

### PATIENTS

Patients 18 years of age or older in whom spontaneous intracerebral hemorrhage was documented by CT scanning within three hours of the onset of symptoms were eligible for enrollment. Exclusion criteria included a score of 3 to 5 on the Glasgow Coma Scale (indicating deep coma)[13]; planned surgical evacuation of hematoma within 24 hours after admission; secondary intracerebral hemorrhage related to aneurysm, arteriovenous malformation, trauma, or other causes; known use of oral anticoagulant agents; known thrombocytopenia; history of coagulopathy, acute sepsis, crush injury, or disseminated intravascular coagulation; pregnancy; preexisting disability (a score greater than 2 on the modified Rankin Scale[14] before the onset of intracerebral hemorrhage); and symptomatic thrombotic or vaso-occlusive disease (i.e., angina, claudication, deep-vein thrombosis, or cerebral or myocardial infarction) within 30 days before the onset of symptoms of intracerebral hemorrhage. Midway through the trial, the last criterion was amended to exclude patients with any history of thrombotic or vaso-occlusive disease.

### STUDY INTERVENTION

Patients were randomly assigned to receive a single intravenous dose of 40 μg, 80 μg, or 160 μg per kilogram of rFVIIa (NovoSeven, Novo Nordisk) or placebo. Randomization was performed in blocks of four patients by means of sequentially numbered, identical-appearing containers. Treatment was given within one hour after the baseline CT and no later than four hours the onset of symptoms. The study drug was supplied as a freeze-dried powder in vials containing either rFVIIa or placebo and was reconstituted in sterile water before being administered intravenously over a period of one to two minutes. The dose was calculated on the basis of estimated body weight. It was recommended that medical management conform with American Heart Association guidelines.[2]



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### CT IMAGE ANALYSIS

Follow-up CT scanning was performed at 24 and 72 hours after study treatment (with a window of 3 hours before and after these times). When a follow-up CT scan was not available within the specified 24-hour period, the first follow-up scan obtained within 48 hours was analyzed, when one was available. Digital CT data were transmitted to an imaging laboratory (Bio-Imaging Technologies) and analyzed in random order with the use of Analyze software (Mayo Clinic) by two neuroradiologists who were blinded to the treatment assignments. The volumes of intracerebral hemorrhage, intraventricular hemorrhage, and edema were calculated with use of standard planimetric techniques.[11]

### CLINICAL ASSESSMENTS

Clinical assessments were performed on enrollment, at the time the study drug was given, 1 and 24 hours after the study drug was given, on days 2, 3, and 15 (or at discharge, if that occurred earlier), and on day 90. The extent of neurologic deficit was assessed during hospitalization with use of the Glasgow Coma Scale[13] and the National Institutes of Health Stroke Scale (NIHSS).[15] Global outcomes at 90 days were assessed with use of the modified Rankin Scale (on which 0 indicates full recovery and 6 indicates death)[14] and the Extended Glasgow Outcome Scale (E-GOS, on which 8 indicates minimal or no disability and 1 indicates death),[16] limitation of the ability to perform activities of daily living with the Barthel Index (on which 100 indicates independence in activities of daily living and 0 indicates that the patient is bedridden and completely dependent),[17] and neurologic impairment with the NIHSS (on which 0 indicates no neurologic deficit and 42 indicates coma and quadriplegia). In the analyses of global outcomes, death and complete dependence on others (indicated by modified Rankin Scale scores of 4 to 6 and E-GOS scores of 1 to 4, respectively) were combined as a single poor-outcome category to control for variations in the tendency to withdraw life support and in order to obviate the possibility that rFVIIa might appear superior to placebo because patients who might otherwise have died had survived with severe disability.

### SAFETY ASSESSMENTS

We recorded the details of all adverse events until the time of discharge and all serious adverse events until day 90. All serious adverse events were reported to an independent data and safety monitoring board within 24 hours. The data and safety monitoring board performed an interim analysis after every 40 patients were enrolled, comparing the proportion dead or severely disabled (defined by a modified Rankin Scale score of 4 to 6 on day 15) in the combined rFVIIa-treatment group with that in the placebo group. The main safety outcome measure was the frequency of thromboembolic serious adverse events at day 90.

### STATISTICAL ANALYSIS

All analyses were based on the intention-to-treat principle and were conducted according to a prespecified statistical-analysis plan. The primary efficacy end point was the change in the volume of intracerebral hemorrhage, expressed as a percentage, from baseline to 24 hours in the three rFVIIa-treatment groups as compared with the placebo group. This study had sufficient power to detect a relative reduction of 56 percent in the growth of the hematoma (from 32 percent in the placebo group to 14 percent with active treatment) in any one of the three rFVIIa-treatment groups, as compared with placebo, on the basis of a two-sided Wilcoxon rank-sum test, with beta=0.80 and alpha=0.0167, an estimated standard deviation of 33 percent, and a 20 percent dropout rate.

Lesion volumes on CT were analyzed with use of generalized linear mixed models to yield estimated mean values. The patient and the readers (two neuroradiologists) were included as random effects, and the baseline volume of intracerebral hemorrhage, the time from the onset of symptoms to CT, and the time from CT to study treatment were included as fixed-effects covariates. Percent changes in the volume of intracerebral hemorrhage and of intracerebral hemorrhage and intraventricular hemorrhage combined were log-transformed to obtain normality after the addition of 100 to eliminate negative values. The volumes of all lesions found on CT were compared with use of a threshold of significance of 0.0167 (with Bonferroni's correction for three doses of rFVIIa as compared with placebo). The threshold of significance for all other comparisons was 0.05.

Patients who died before day 90 were assigned the worst possible scores for measures of neurologic impairment and functional outcome. For surviving patients with missing outcome data, the last observation was carried forward. The scores on the E-GOS and modified Rankin Scale were analyzed in a cumulative logit model, with adjustment for age, baseline intracerebral-hemorrhage volume, lo-



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**Table 1. Baseline Characteristics and Timing of Treatment.***

| Variable | Placebo (N=96) | rFVIIa | | |
|---|---|---|---|---|
| | | 40 μg/kg (N=108) | 80 μg/kg (N=92) | 160 μg/kg (N=103) |
| Age (yr) | 68±12 | 67±12 | 65±12 | 64±13 |
| Male sex (%) | 53 | 63 | 61 | 67 |
| Race or ethnic group (%) | | | | |
| White | 81 | 77 | 86 | 80 |
| Asian or Pacific Islander | 15 | 19 | 10 | 15 |
| Other | 4 | 5 | 4 | 6 |
| Location of hemorrhage (%)† | | | | |
| Putamen or globus pallidus | 58 | 54 | 44 | 55 |
| Thalamus | 30 | 33 | 40 | 31 |
| Lobar hemisphere | 21 | 18 | 25 | 18 |
| Cerebellum | 2 | 4 | 1 | 3 |
| Pons or midbrain | 6 | 4 | 4 | 2 |
| GCS score‡ | | | | |
| Median | 14 | 14 | 15 | 14 |
| Range | 3–15 | 8–15 | 6–15 | 6–15 |
| NIHSS score§ | 15±6 | 14±6 | 12±6 | 14±6 |
| Systolic BP at time of treatment (mm Hg) | 172±32 | 170±28 | 178±32 | 172±30 |
| Time from onset to treatment (min) | 165±33 | 173±32 | 167±32 | 165±32 |
| Treated <3 hr after onset (%) | 72 | 62 | 76 | 71 |

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding. GCS denotes Glasgow Coma Scale, NIHSS National Institutes of Health Stroke Scale, and BP blood pressure.
† More than one region could be involved in a given patient.
‡ Scores range from 15 (normal) to 3 (deep coma).
§ Scores range from 0 (normal) to 42 (coma with quadriplegia).

cation of the hemorrhage, and baseline functional status (for the modified Rankin Scale score only). Wilcoxon rank-sum tests were used to compare scores on the Barthel Index and NIHSS. Fisher's exact test was used to compare the frequency of arterial, venous, and all thromboembolic serious adverse events in the four treatment groups at day 90. All analyses were performed with use of SAS software, version 8.2 (SAS Institute) on a Unix platform.

## RESULTS

### BASELINE CHARACTERISTICS

Four hundred patients underwent randomization; 1 subsequently withdrew consent, leaving 399 patients for analysis. Twelve percent of the patients with intracerebral hemorrhage (199 of 1636) were enrolled at the 38 study sites that collected complete screening data. Baseline characteristics for the four treatment groups were similar (Table 1). The mean age was 66 years (range, 35 to 91), 61 percent of the patients were male, and the majority of patients (81 percent) were white. The median Glasgow Coma Scale score was 14 (range, 3 to 15), and the mean NIHSS score was 14 (range, 2 to 35). The most frequent area of involvement was the putamen or globus pallidus (52 percent), followed by the thalamus (33 percent) and lobar regions (20 percent). The mean intracerebral-hemorrhage volume at baseline (24 ml; range, 0.4 to 153) was similar in the four groups (Table 2).

The mean interval from the onset of symptoms to the baseline CT scan was 114±35 minutes, the mean interval from CT to treatment was 54±21 minutes, and the mean time from onset to treatment was 167±32 minutes. Seven percent of patients were treated within two hours after onset and 63 percent within three hours; only one patient was treated outside the four-hour time window. The timing of treatment was similar in the four treatment groups (Table 1).

### RADIOGRAPHIC OUTCOMES

A total of 396 baseline CT scans and 384 24-hour CT scans (representing 96 percent of all patients) were available for analysis. In 48 patients (12 percent of all patients) the follow-up CT was obtained more than 3 hours before the specified time of 24 hours after study treatment, and in 17 (4 percent) it was obtained more than 3 hours after the specified time. The intraclass correlation coefficients between the two readers were 0.96 for intracerebral hemorrhage and 0.74 for edema.

The primary outcome measure, the mean percent increase in the volume of intracerebral hemorrhage, was significantly lower in the group given 160 μg of rFVIIa per kilogram than in the placebo group; this was not the case for the groups given 40 μg and 80 μg per kilogram (Table 2). This effect was most pronounced at higher doses (P=0.02 by the global test for trend), and the difference between the combined rFVIIa groups and the placebo group was significant. The mean absolute increase in the volume of intracerebral hemorrhage was also significantly smaller with rFVIIa than with placebo (4.2 vs. 8.7 ml), a relative reduction of 52 percent. Again, a dose–response effect was evident (P for



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**Table 2. Lesion Volumes on CT According to Study Group.***

| Variable | Placebo (N=96) | rFVIIa | | | |
|---|---|---|---|---|---|
| | | 40 μg/kg (N=108) | 80 μg/kg (N=92) | 160 μg/kg (N=103) | Combined (N=303) |
| **Volume of ICH** | | | | | |
| At baseline — ml | 24±22 | 22±22 | 23±24 | 26±30 | 24±26 |
| At 24 hr — ml | 32±29 | 26±29 | 28±31 | 28±32 | 27±30 |
| Estimated mean relative increase from baseline — % (98.3% CI) | 29 (16 to 44) | 16 (4 to 28) | 14 (2 to 27) | 11 (0 to 23) | 14 (7 to 21) |
| P value, vs. placebo | — | 0.07 | 0.05 | 0.02† | 0.01† |
| Estimated mean absolute increase from baseline — ml (98.3% CI) | 8.7 (4.9 to 12.4) | 5.4 (1.7 to 9.0) | 4.2 (0.3 to 8.0) | 2.9 (−0.8 to 6.6) | 4.2 (2.0 to 6.3) |
| P value, vs. placebo | — | 0.13 | 0.04 | 0.008† | 0.01† |
| **Volume of ICH plus IVH** | | | | | |
| At baseline — ml | 29±29 | 25±24 | 27±28 | 30±31 | 27±28 |
| At 24 hr — ml | 38±37 | 30±34 | 33±36 | 33±36 | 32±36 |
| Estimated mean relative increase from baseline — % (98.3% CI) | 31 (18 to 46) | 16 (4 to 28) | 14 (2 to 27) | 13 (2 to 25) | 14 (7 to 21) |
| P value, vs. placebo | — | 0.04 | 0.03 | 0.01† | 0.006† |
| Estimated mean absolute increase from baseline — ml (98.3% CI) | 10.8 (6.0 to 15.6) | 7.2 (2.5 to 11.8) | 5.1 (0.1 to 10.0) | 4.0 (−0.8 to 8.7) | 5.4 (2.7 to 8.2) |
| P value, vs. placebo | — | 0.19 | 0.05 | 0.02† | 0.02 |
| **Volume of ICH plus IVH plus edema** | | | | | |
| At 72 hr — ml | 69±58 | 56±48 | 50±43 | 51±42 | 53±45 |
| Estimated mean difference from placebo — ml (98.3% CI) | — | −6.5 (−17.1 to 4.0) | −12.2 (−23.2 to 1.3) | −14.4 (−25.1 to −3.7) | −11.0 (−19.7 to −2.1) |
| P value, vs. placebo | — | 0.14 | 0.008† | 0.001† | 0.003† |

* Plus–minus values are means ±SD. For estimated mean differences, 98.3 percent confidence intervals (CIs) are derived from a generalized linear mixed model with the patient and the reader as random effects and baseline volume of intracerebral hemorrhage (ICH), time from onset to CT, and time from CT to treatment as fixed effects. IVH denotes intraventricular hemorrhage. Negative values for absolute changes (in milliliters) indicate a decrease in volume. The numbers of patients for whom CT scans were not available at 24 and 72 hours were 2 and 1 in the placebo group and 7 and 5, 5 and 3, and 4 and 2 in the groups given 40 μg, 80 μg, and 160 μg of rFVIIa per kilogram, respectively.

† The comparison was statistically significant according to the prespecified Bonferroni-corrected threshold of P=0.0167.

trend=0.007), and the absolute increase in the group given 160 μg per kilogram was significantly lower than that in the placebo group. Similar results were obtained when percent changes in total intracranial blood volume (intracerebral hemorrhage plus intraventricular hemorrhage) were analyzed (P for trend=0.02) and when absolute changes were analyzed (P for trend=0.01) (Table 2).

The hemostatic effect of rFVIIa was more evident when treatment was given within three hours after the onset of symptoms. In this subgroup (269 patients), the mean increase in volume of intracerebral hemorrhage was 34 percent for the placebo group, as compared with 13 percent for the rFVIIa-treated patients (P=0.004), and the absolute increase in volume of intracerebral hemorrhage was 10.7 ml for the placebo group, as compared with 4.4 ml for the rFVIIa-treated patients (P=0.009). Among those treated more than three hours after onset (115 patients), the mean increase in intracerebral-hemorrhage volume was 14 percent for the placebo group, as compared with 16 percent for the rFVIIa groups (P=0.86), and the absolute increase was 3.1 ml, as compared with 3.8 ml (P=0.76).

The total lesion volume (intracerebral hemorrhage plus intraventricular hemorrhage plus edema) at 72 hours was reduced by an estimated mean of 11 ml with rFVIIa treatment, as compared with placebo, and a dose–response relationship was again evident (P for trend, <0.001).



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### CLINICAL OUTCOMES

Mortality at three months was 29 percent in the placebo group, as compared with 18 percent in the three treatment groups combined — a relative reduction of 38 percent (P=0.02 by the chi-square test) (Fig. 1 and Table 3). All four outcome scales showed a more favorable global outcome for rFVIIa-treated patients than for those who received placebo, in a dose–response fashion (Fig. 2). The results were significantly different from those in the patients who received placebo for all three doses of rFVIIa, as measured by the modified Rankin Scale and the NIHSS, and for the 80 and 160 μg per kilogram doses, according to the Barthel Index (Table 3). Treatment with rFVIIa more than doubled the odds of improving by one level on the modified Rankin Scale at 90 days and decreased the proportion of patients who died or were severely disabled from 69 percent in the placebo group to 53 percent in the three treatment groups combined, for an absolute reduction of 16 percentage points (95 percent confidence interval, 5 to 27; P=0.004). The E-GOS also showed a favorable effect of rFVIIa treatment on outcome, but this effect was not significant, owing to a large floor effect; overall, approximately three quarters of patients had died or were classified as severely disabled at three months.

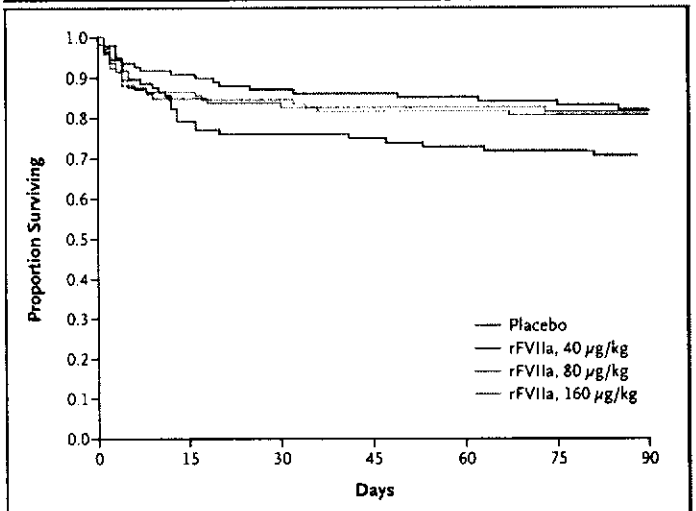


**Figure 1. Survival at 90 Days According to Study Group.**

Mortality was reduced by approximately 35 percent in each rFVIIa group, as compared with that in the placebo group (P=0.10 by the log-rank test comparing all four groups; P=0.02 by the chi-square test for the comparison of the three rFVIIa groups combined with placebo).

### SAFETY

Thromboembolic serious adverse events (Table 3) occurred in 2 percent of the placebo-treated patients, as compared with 7 percent of the rFVIIa-treated patients overall (P=0.12 by Fisher's exact test). There were no arterial thromboembolic serious adverse events in the placebo group; the overall frequency of such events was 5 percent among the rFVIIa-treated patients (P=0.01 by Fisher's exact test). There were seven myocardial ischemic events and nine cases of cerebral infarction; all but four of these occurred within three days of the administration of rFVIIa. Two of the cases of cerebral infarction were massive and fatal, five were moderate in severity and disabling (two of these occurred 26 and 54 days after treatment and were not considered to be related to treatment), and two were asymptomatic.

With the exception of one patient with an anterior-wall myocardial infarction who recovered with sequelae, the cardiac events that occurred in the rFVIIa-treated patients were characterized by small troponin I elevations, non–ST-segment elevation electrocardiographic abnormalities, and good recovery. Thromboembolic serious adverse events that were possibly or probably related to treatment (as opposed to those that were unlikely to be related to treatment) and that were fatal or disabling occurred in 2 percent of rFVIIa-treated patients and in 2 percent of the placebo group.

## DISCUSSION

In this study, rFVIIa given within four hours after the onset of intracerebral hemorrhage significantly reduced subsequent growth of the hemorrhage and improved the clinical outcome, despite a small increase in the frequency of thromboembolic adverse events. Treatment with rFVIIa resulted in reduced growth in the volume of intracerebral hemorrhage, as compared with placebo, by approximately 5 ml at 24 hours, which translated into an 11-ml reduction in total lesion volume at 72 hours, as compared with placebo. This difference was associated with an absolute reduction of 16 percentage points in the risk of death or severe disability (as measured by the modified Rankin Scale) at three months — consistent with the number needed to treat to prevent one unfavorable outcome of slightly more than six.

The patients we treated were typical of those with spontaneous hypertensive intracerebral hemorrhage, but they had slightly smaller hemorrhages and better Glasgow Coma Scale scores than those



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**Table 3. Clinical Outcomes and Thromboembolic Severe Adverse Events at 90 Days According to Study Group.***

| Variable | Placebo (N=96) | rFVIIa | | | |
|---|---|---|---|---|---|
| | | 40 μg/kg (N=108) | 80 μg/kg (N=92) | 160 μg/kg (N=103) | Combined (N=303) |
| **Survival** | | | | | |
| Died — no. (%) | 28 (29) | 19 (18) | 17 (18) | 20 (19) | 56 (18) |
| Odds ratio for survival (95% CI) | — | 1.9 (1.0–3.8) | 1.8 (0.9–3.6) | 1.7 (0.9–3.3) | 1.8 (1.1–3.0) |
| P value | | 0.05 | 0.10 | 0.11 | 0.02 |
| **Modified Rankin Scale†** | | | | | |
| Unfavorable outcome — no. (%) | 66 (69) | 59 (55) | 45 (49) | 56 (54) | 160 (53) |
| Odds ratio for improvement (95% CI) | — | 2.2 (1.1–4.0) | 2.4 (1.3–4.6) | 2.1 (1.1–4.1) | 2.2 (1.3–3.8) |
| P value | — | 0.02 | 0.008 | 0.02 | 0.004 |
| **Extended Glasgow Outcome Scale‡** | | | | | |
| Unfavorable outcome — no. (%) | 78 (81) | 78 (72) | 66 (72) | 77 (75) | 221 (73) |
| Odds ratio for improvement (95% CI) | — | 1.9 (0.9–3.8) | 1.5 (0.7–3.2) | 1.4 (0.7–3.0) | 1.6 (0.9–3.0) |
| P value | — | 0.09 | 0.28 | 0.36 | 0.14 |
| **Barthel Index§** | | | | | |
| Median score | 25.0 | 55.0 | 67.5 | 55.0 | 60.0 |
| P value | — | 0.07 | 0.01 | 0.02 | 0.006 |
| **National Institutes of Health Stroke Scale¶** | | | | | |
| Median score | 12.5 | 6.0 | 5.0 | 7.0 | 6.0 |
| P value | — | 0.03 | 0.004 | 0.02 | 0.008 |
| **Thromboembolic serious adverse events — no. (%)** | | | | | |
| Total | 2 (2) | 7 (6) | 4 (4) | 10 (10) | 21 (7) |
| Arterial | 0 | 6 (6) | 2 (2) | 8 (8) | 16 (5) |
| Venous | 2 (2) | 1 (1) | 2 (2) | 2 (2) | 5 (2) |

* Odds ratios are for survival as compared with the placebo group. CI denotes confidence interval. Outcome scores at day 15 were used according to the principle of the last observation carried forward when scores at day 90 were missing. Scores on the modified Rankin Scale and the Extended Glasgow Outcome Scale were not available for one patient in the group given 80 μg of rFVIIa per kilogram; otherwise, outcome scores were available for all patients. The numbers of patients who had one or more outcome scores carried forward from day 15 were 7, 6, 5, and 2 in the placebo, 40 μg, 80 μg, and 160 μg per kilogram groups, respectively. Odds ratio for improvement is the likelihood of improving by one scale level, as compared with that in the placebo group, with control for age, baseline intracerebral-hemorrhage volume, and location of the intracerebral hemorrhage. Modified Rankin Scale scores of 4 to 6 and Extended Glasgow Outcome Scale scores of 1 to 4 were pooled as a single category indicating an unfavorable outcome (death or severe disability).

† Scores of 4 to 6 (defined as an unfavorable outcome) indicate death or survival with severe disability (bedbound and incontinent) or moderate-to-severe disability (unable to walk without assistance).

‡ Scores of 1 to 4 (defined as an unfavorable outcome) indicate death or inability to follow commands, care for oneself at home, or shop or travel locally without assistance.

§ A score of 100 indicates complete independence in activities of daily living, and 0 indicates total dependence or death. The treatment groups were compared with the placebo group with use of the Wilcoxon rank-sum test.

¶ A score of 0 indicates no neurologic deficit, and a score of 42 coma and quadriplegia or death. The treatment groups were compared with the placebo group with use of the Wilcoxon rank-sum test.

in other series, owing to our exclusion criteria.[3,4] Accordingly, the 29 percent mortality rate in our placebo group was slightly lower than what is typically found in hospital registries and population-based studies.[1,3,4] Thirty-two percent of placebo-treated patients had substantial growth in the volume of intracerebral hemorrhage, defined as an increase of more than 33 percent or more than 12.5 ml from baseline (data not shown); this rate is similar to those in previous studies.[5-8]

The doses of rFVIIa that we studied in this dose-ranging proof-of-concept trial ranged from approx-



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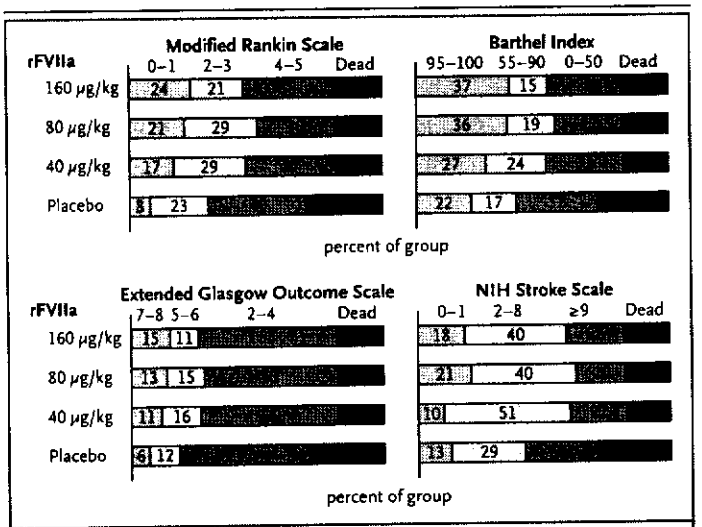


**Figure 2. Outcome at 90 Days According to Study Group.**

Scores of 0 to 1 on the modified Rankin Scale, 7 to 8 on the Extended Glasgow Outcome Scale, 95 to 100 on the Barthel Index, and 0 to 1 on the National Institutes of Health (NIH) Stroke Scale indicate a favorable outcome. Percentages may not total 100 because of rounding. Twenty patients (5.0 percent) were alive but lacked complete outcome data at 90 days, and thus had some or all scores at day 15 carried forward.

imately half to twice the currently labeled dose of 90 μg per kilogram for bleeding related to hemophilia. Treatment with rFVIIa resulted in a relative reduction of approximately 50 percent in the growth of hemorrhage, and a dose–response effect was evident, with the smallest effect at 40 μg per kilogram and the strongest at 160 μg per kilogram.

The timing of treatment also had a powerful effect on the capacity of rFVIIa to limit the growth of intracerebral hemorrhage; the best results were seen when patients were treated within three hours after the onset of symptoms. This suggests that active bleeding occurs in a large proportion of patients with intracerebral hemorrhage within the first few hours after onset and rapidly diminishes over time. Our subgroup analysis of patients treated more than three hours after onset was underpowered; accordingly, our data permit us to conclude only that treatment with rFVIIa within four hours after onset is beneficial.

The precise mechanism by which rFVIIa arrests bleeding in patients with acute intracerebral hemorrhage is not fully understood. After blood-vessel damage and local initiation of the coagulation cascade, the administration of rFVIIa enhances thrombin generation on the surface of activated platelets, leading to accelerated formation of a fibrin clot.[18] It seems most likely that the administration of rFVIIa after intracerebral hemorrhage accelerates thrombosis within ruptured small penetrating arteries or arterioles. Although the half-life of rFVIIa is only 2.6 hours,[19] a sustained hemostatic effect may occur after a single dose because the clot that forms is denser than normal and more resistant to fibrinolysis.[20]

Mortality was significantly reduced, by 38 percent, with rFVIIa treatment. Both the 80 μg and the 160 μg per kilogram doses of rFVIIa significantly improved global outcomes as measured on three of the four standard scales that we evaluated. Although we did not record when decisions were made to withhold or withdraw life support, our use of the combination of death and severe disability as a single category made it unlikely that decisions to withdraw life-sustaining treatment influenced the results.

Arterial thromboembolic serious adverse events occurred significantly more frequently with rFVIIa treatment than with placebo, primarily in the form of myocardial ischemic events and cerebral infarction within three days after the study drug was given. The majority of patients recovered from these complications, and the overall frequency of fatal or disabling thromboembolic serious adverse events did not differ significantly between the rFVIIa and the placebo groups.

In summary, ultra-early hemostatic therapy with rFVIIa limits the growth of hemorrhage, reduces mortality, and improves functional outcomes after intracerebral hemorrhage. Until additional data on safety are available, however, rFVIIa should be administered with caution to patients with intracerebral hemorrhage who have risk factors for thromboembolic disease. Additional research is needed to identify patients at high risk for thromboembolic complications, to define the optimal therapeutic window, and to test rFVIIa for anticoagulation-induced intracerebral hemorrhage.[21]

Supported by Novo Nordisk, Bagsvaerd, Denmark.

Presented in part at the Fifth World Stroke Congress, Vancouver, B.C., Canada, June 26, 2004.

Drs. Brun and Skolnick and Ms. Begtrup are employees of Novo Nordisk and report being stockholders in the company. Dr. Mayer reports having received research support from Novo Nordisk. Drs. Mayer, Broderick, Davis, Diringer, and Steiner report having received consulting fees from Novo Nordisk, and Drs. Mayer, Davis, Diringer, and Steiner report having received lecture fees from Novo Nordisk.

We are indebted to the study coordinators, the nurses and physicians in the emergency departments and intensive care units, and the patients and families who supported this trial.



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## APPENDIX

The following participated in the Recombinant Activated Factor VII Intracerebral Hemorrhage Trial: **Steering Committee** — S.A. Mayer, New York (chair); J. Broderick, Cincinnati; N.C. Brun, Bagsvaerd, Denmark (nonvoting); S. Davis, Melbourne, Australia; M.N. Diringer, St. Louis; B.E. Skolnick, Princeton, N.J. (nonvoting); and T. Steiner, Heidelberg, Germany; **Statistician** — K. Begtrup, Bagsvaerd, Denmark; **Data and Safety Monitoring Board** — T.G. Brott, Jacksonville, Fla. (chair); K. Asplund, Stockholm; T.P. Bleck, Charlottesville, Va.; M. Escobar, Houston; and I. Scharrer, Frankfurt, Germany; **Neuroradiologists** — R. Zimmerman, New York; J. Maldjian, Winston-Salem, N.C; **Contract Research Organization** — Quintiles Transnational (A. Lopez, global project manager); **Clinical Centers — Australia:** S. Davis, Royal Melbourne Hospital, Parkville, Vic.; G. Donnan, Austin and Repatriation Medical Centre, Heidelberg, Vic.; D. Freilich, Western Hospital, Footscray, Vic.; R. Gerraty, St. Vincent's Hospital, Fitzroy, Vic.; T. Kimber, Royal Adelaide Hospital, Adelaide, S.A.; D. Schultz, Flinders Medical Centre, Bedford Park, S.A.; **Austria:** F. Fazekas, Universitat Klinik Graz, Graz; **Belgium:** S. Blecic, Hospital Erasme, Brussels; P.P. De Deyn, Algemeen Ziekenhuis Middelheim, Antwerp; V. Thijs, U.Z. Gasthuisberg, Leuven; **Canada:** P. Bailey, Saint John Regional Hospital, Saint John, N.B.; M. Hill, Foothills Hospital, Calgary, Alta.; D. Selchen, Trillium Health Centre, Mississauga, Ont.; C. Voll, Royal University Hospital, Saskatoon, Sask.; A. Woolfenden, Vancouver General Hospital, Vancouver, B.C.; **Croatia:** V. Demarin, Clinical Hospital Sestre Milosrdnice, Zagreb; **Denmark:** G. Andersen, Aarhus University Hospital, Aarhus; G. Boysen, Bispebjerg Hospital, Copenhagen; **Finland:** M. Kaste, Helsingin Yliopistollienen, Haartmaninkatu; **Germany:** O. Busse, Klinikum Minden, Minden; A. Ferbert, Universitaetsklinikum Kassel, Kassel; M. A. Grond, Kreiskrankenhaus Siegen, Siegen; R. Haberl, Steadt. Krakenhaus, Munich; M. Hennerici, Klinikum Mannheim, Mannheim; D. Schneider, Universitaets-Klinikum der Universitaet Leipzig, Leipzig; T. Steiner, Universitaetsklinik Heidelberg, Heidelberg; **Italy:** C. Argentino, Universitá La Sapienza, Rome; V. Gallai, Universitá di Perugia, Perugia; D. Guidetti, Azienda Hospedaliera Santa Maria, Reggio Emilia; G. Miceli, Istituto di Ricovero e Cura a Carattere Scientifico, C. Mondino UC Malattie, Pavia; **Malaysia:** R.A. Adman Zurin, Universiti Kebangsaan Malaysia, Kuala Lumpur; **the Netherlands:** J.U.R. Niewold, Scheper Ziekenhuis, Emmen; M. Vermeulen, Academisch Medisch Centrum, Amsterdam; **New Zealand:** C. Anderson, Middlemore Hospital, Auckland; A. Barber, Auckland Hospital, Auckland; **Norway:** U. Waje-Andreassen, Haukeland Sykehus, Bergen; **Singapore:** I. Ng, National Neuroscience Institute; C. Ning, National University Hospital; **Spain:** A. Chamorro, Hospital Clinic I Provincial de Barcelona, Barcelona; A. Dávalos, Hospital Universitario de Girona Dr. Josep Trueta, Girona; J. Egido, Hospital Clínico San Carlos, Madrid; J.V. Osorio, Hospital General Universitario Gregorio Marañón, Madrid; J.A. Sabin, Hospital Vall d'Hebrón, Barcelona; **Sweden:** M. Callander, Universitetssjukhuset I, Linköping; T.-B. Källi, Södersjukhuset, Stockholm; N.G. Walgren, Karolinska Sjukhuset, Stockholm; **Switzerland:** J. Bogousslavsky, Centre Hospitalier Universitaire Vaudois Service de Neurologie, Lausanne; **Taiwan:** Y.-H. Chiang, Tri-Service General Hospital, Taipei; T.-K. Lin, Chang Gung Memorial Hospital, Taoyuan; Y.-K. Tu, College of Medicine and Hospital National Taiwan University, Taipei; **United Kingdom:** J. Barrett, Arrowe Park Hospital, Merseyside; G. Ford, University of Newcastle, Newcastle upon Tyne; M.-J. Macleod, Aberdeen Royal Infirmary, Aberdeen; K. Richardson Lees, Western Infirmary, Glasgow; **United States:** B.F. Fitzsimmons, Columbia University Medical Center, New York; C. Graffagnino, Duke University Medical Center, Durham, N.C.; D. Green, Queen's Medical Center, Honolulu; J. Grotta, University of Texas Medical School, Houston; S.E. Kasner, Hospital of the University of Pennsylvania, Philadelphia; R. Libman, Long Island Jewish Medical Center, New Hyde Park, N.Y.; T. Lowenkopf, Oregon Stroke Center, Portland; F. McGee, Neurological Associates, Richmond, Va.; B. Meyer, University of California–San Diego Stroke Center, San Diego; J. Rosand, Massachusetts General Hospital, Boston; C. Wijman, Stanford Stroke Center, Palo Alto, Calif.

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June 23, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1500-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: **CMS-1500-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule.**

Dear Dr. McClellan:

I appreciate this opportunity to comment on the proposed rule for the FY 2005 Inpatient Prospective Payment System (IPPS) on behalf of Sturdy Memorial Hospital. I am very concerned that several of your proposed changes to the IPPS will have significant negative implication on the way the hospital cares for Medicare beneficiaries and I am providing specific comments on those proposals. I am particularly concerned about the proposed expansion of the post-acute care transfer policy.

**PROPOSED EXPANSION OF THE POST-ACUTE CARE TRANSFER POLICY**

In the proposed rule, CMS discusses the possibility of expanding the policy from 30 DRGs to either 223 DRGs (later revised to 231) or all DRGs. CMS proposes to expand the list of DRGs subject to this policy by making substantial revisions to the DRG selection criteria with little justification or evidence.

Section 1886(d)(4)(J) of the Social Security Act directs CMS to focus on those DRGs that have a high volume of discharges to post-acute care and a disproportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have *disproportionate* use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to a post-acute care in FY 2004. Clearly 88 percent of DRGs with *any* post-acute care use cannot have *disproportionate* use.

The revised criteria also do not address specific changes in hospital behavior that might indicate an attempt to take advantage of the payment system. No backup data or arguments are provided to justify the changes. For example:

- CMS proposes a sharp drop in the post acute transfer volume threshold need for a DRG to be included in the policy (from 14000 to 2000) which is an 85.7% drop. CMS also proposes to add a 20% transfer rate to PAC as a criterion for inclusion. Both these thresholds seem to have been

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arbitrarily set to achieve the desired budget results. CMS is capturing DRGs that are not at all *high-volume*. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2070 discharges to post-acute care as compared to DRG 544 (major joint replacement or reattachment of lower extremity) which has 349,085 discharges to post-acute care. It cannot be argued that while DRG 473 does not have a *high-volume* of discharges to post-acute care, it still has *disproportionate* use. Only 22.7 percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. **CMS' proposed criteria cast far too wide of a net and captures far more DRGs than appropriate.**

- CMS proposes to remove the declining length of stay criterion which is directly relevant to the issue CMS claims to be addressing by expanding the PAC transfer policy. The stated purpose of the IPPS transfer payment policy is to avoid providing an incentive for a hospital to transfer patients to another hospital early in the patients' stay in order to minimize costs while still receiving the full DRG payment. The removal of the LOS criterion seems to have been done to justify an expansion of the policy where there is no evidence that hospitals are changing behavior (transferring patients earlier) to take advantage of the payment system. In fact, in implementing the policy for the current 10 DRGs, CMS included an analysis showing that across almost all lengths of stay for each of the 10 DRGs, hospitals would, on average, be paid in excess of their costs even after the implementation of the provision, I have not seen any such data for the new proposed 231 DRGs. The Health Economics Research, Inc. in its report of July 31, 2000 showed that short-stay post-acute transfer cases are 7.4 percent more costly than short-stay non-post acute care transfer cases. **While the length of stay may be shorter, the level of services provided during the stay is more intense and costly.**

As I have argued in the past, the PPS payment system is based on a system of "averaging" where cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy simply reduces payments to short stay low cost cases while not simultaneously increasing payments for long stay cases. This makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay. For all practical purposes, such an extensive expansion of the post-acute transfer policy acts as an across-the-board reduction in Medicare payments. As a result, hospitals would be penalized for providing efficient care in the setting that is most appropriate for the patient. It provides a perverse incentive to extend the stay of the patient beyond that which is clinically appropriate, despite the fact that more specialized attention may be provided in a PAC setting.

**I strongly object to an expansion of the post-acute care transfer policy, which is not in the best interests of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting.**

## UNDERESTIMATION OF THE HOSPITAL MARKET BASKET

The hospital update is based on a market basket factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish inpatient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate inflationary update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

I am concerned that for 7 of the last 8 years, ***the market basket projection has been lower than the actual increase***. While the market basket was over-estimated for a number of years prior to that time, a methodology change was made in 1998 that appears to have over corrected for the previous estimations. CMS reports that, based on the most recent data, the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. I am concerned that ***the methods used to project the market basket increase are flawed and fail to provide a reliable estimate of hospital cost increases.***

**I request that CMS review the methodology that was used to determine the projected FY 2005 market basket and revise it for the FY 2006 projection and to make the details of the calculation available to the public.**

## WAGE INDEX

Wage Index Calculation Change

The inpatient PPS proposed rule for 2006 contained a change in the wage index calculation. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 in the *Federal Register*.

The change is in the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

1. Determine the ratio of overhead hours to revised hours.
2. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step 1 by wage-related costs.
3. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in step 1. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step 1, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

I am concerned that CMS would make such a change to the calculation of the wage index with out any discussion. This change does not appear to make sense and I request that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers should be given an opportunity to comment on this revision to

the methodology *before* it is implemented. I believe that this methodological revision will have a significant impact on the wage indexes for some hospitals. **Accordingly, I believe that CMS should return to the established methodology and go through the full notice and comment process before making such a change.**

Occupational Mix Adjustment-Future Data Collection

The occupational mix adjustment to the wage index was intended to control for the effect of hospitals' employment choices rather than geographic differences in the costs of labor. CMS has indicated that the results of the adjustment were counter to the agency's expectations and that nearly one-third of rural areas and over one-half of urban areas would see a decrease in their wage index as a result of this adjustment. Given the expense, administrative effort and time that hospitals have to put into filling out yet another detailed survey and the fact the there are ongoing concerns regarding the data and the impact, **I urge CMS to work with Congress to eliminate this requirement and the adjustment.**

**DSH ADJUSTMENT DATA**

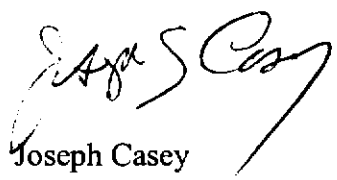
Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. I believe that this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine whether the data based on the federal fiscal year or their own fiscal year is advantageous. **I support CMS' plans to release a MedPAR limited data set for both SSI and Medicare but I strongly object to CMS' decision not to make available Medicaid information**. Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA, states that the Secretary of Health and Human Services must arrange to provide information hospitals need to calculate the Medicare DSH payment formula. This same section in the version of the MMA passed by the House of Representatives states specifically that the Secretary is required to provide the information to hospitals so they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital field has brought this issue regarding the problems of obtaining Medicaid information from the state programs to the attention of CMS for a number of years. CMS then as now, continues to ignore this problem.

CMS states in the rule that it believes hospitals are best situated to provide and verify Medicaid eligibility information and that the mechanisms are currently in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting, and justifying the Medicaid days is problematic, complex, time-consuming and labor intensive. Moreover, the penetration of Medicaid managed care can add an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals. *Consultants with expertise in this field are being highly paid to calculate DSH for hospitals. This money that should be going toward providing care rather than paying consultants to work through the complexities that currently exist in gathering this information.*

**I recommend that CMS impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information and that CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state, and that the state make this information available to the providers and contractor audit staff.**

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (508) 236-8150.

Sincerely,



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June 22, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W. Room 445-G
Washington, D.C. 20201

**Reference: CMS-1500- P Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates**

Dear Dr. McClellan:

The North Carolina Hospital Association (NCHA) represents more than 110 acute care hospitals in the State of North Carolina. NCHA welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed inpatient payment rules published May 4, 2005.

Market Basket Projections and Increases

CMS has increased the PPS standardized amount by the projected market basket since 1998. However, the actual market basket increase and the projections have grown further apart as the years pass. The accumulated differences of the actual market basket and the projections between 1998 and 2005 have reduced payments to hospitals by 3.8%. A reliable projection methodology is vital to ensure equitable payments to hospitals. NCHA recommends that a review of the methodology used to make the projections should be undertaken so as to narrow the gap and allow hospitals the opportunity to be reimbursed at a level which reflects the real cost of doing business. Additionally, we urge CMS to make the details of the calculation available to the public.

Wage Index Calculation Change Core Based Statistical Area Calculations

NCHA member hospitals have expressed concern regarding the method used by CMS for changing the formula used to calculate the proportions to be used to exclude overhead dollars and hours related to excluded units. The change in the calculation for overhead wage-related cost is made up of three steps:

- Step 1: Determine the ratio of overhead hours to revised hours;
- Step 2: Compute overhead wage-related cost by multiplying the overhead hour's ratio from step 1 by wage related costs;
- Step 3: Multiply the overhead wage-related cost by the excluded hour's ratio.

The change in the calculation occurred in step 1. For fiscal year 2006, the calculation for revised hours was changed to subtract excluded areas (lines 8 and 8.01). With the change, a higher ratio for step 1 was achieved which resulted in an increase in the overhead cost allocated to excluded areas. The change ultimately lowers the hospitals' average hourly rate.

CMS did not propose this change directly, did not discuss why or what purpose it serves, or why the two proportions are different. This change disproportionately affects certain CBSAs more significantly than others. Since wage index is a zero sum formula, NCHA is interested in the lack of formal process which CMS did not follow. We believe all changes which affect reimbursement to hospitals should be outlined and explained in detail prior to implementation, and follow the regulations as to a comment period. Further impacts to hospitals with regard to the arbitrary change include the inability to apply for reclassification for the fiscal year 2006 once hospitals have seen the results of the change in calculation. If CMS believes the change in calculation reflects a more appropriate method, they should outline the reasons and go through the full notice and comment process before making such a change. If this is the intent of CMS, the process needs to begin now in order to allow hospitals complete advantage for filing the upcoming reclassification for the fiscal year 2007 payments which are due on August 30. NCHA strongly encourages CMS to withdraw the change for the fiscal year 2006.

DRG Reclassifications

Our member hospitals expected to see an expansion in DRGs to cover a number of the high dollar drugs used in advance cardiac life saving, such as tissue plasmenogen activator (TPA). Upon further review of your rule, NCHA has determined that CMS may not be evaluating all diagnoses and procedures that could possibly affect a patient's severity of illness and/or the resources utilized. The current DRG grouper only considers 9 diagnoses and up to 6 procedure codes. Hospitals submit claims to their respective fiscal intermediary in a HIPAA compliant electronic 837I transaction which allows 23 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the grouper to assign a DRG. It is important for inpatient acute hospitals whose patients are medically complex and have multiple illnesses beyond the 9 diagnoses allowed by CMS. Moreover, until recently psychiatric hospitals have not had an established list of comorbid conditions qualifying for comorbidity adjustments, and thus have not utilized the software tools employed by general acute care hospitals for years to sort and rearrange secondary diagnosis codes so that all comorbid conditions possibly affecting the DRG grouping are prioritized.

NCHA urges CMS to modify the DRG grouper and instruct fiscal intermediaries to expand the number of diagnoses from 9 to 23, and the number of procedures from 6 to 25, in order to include all reportable diagnoses and procedures in the DRG calculation,

Post-Acute Care Transfers

Medicare patients in certain DRGs who are discharged to a post-acute care setting – such as rehabilitation hospitals and units, long-term care hospitals, or skilled nursing facilities – or are discharged within three days to home health services, are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per-diem rate rather than a fixed DRG amount, up to the full inpatient PPS rate.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient PPS is based on a system of averages. Cases with higher-than-average lengths of stay tend to be paid less than costs, while cases with shorter-than-average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients who receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay. This misguided approach to expand the policy to 231 DRGs will have a devastating impact on North Carolina hospitals by reducing overall payments by an estimated $26.7 million when the effects

on disproportionate share hospital (DSH), indirect medical education (IME), capital and outliers payments are considered.

The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care, at the right time, in the right place. The policy disadvantages hospitals that make sound clinical judgments about the best setting of care for patients, and this setting is often outside of the hospital's four walls. Hospitals should not be penalized for greater-than-average efficiency. Particular facilities, in regions of the country where managed care has yielded lower lengths of hospital stay for all patients, are disproportionately penalized.

Furthermore, it is unclear whether this policy will end up costing the Medicare program, as a whole, more money. Patients who are kept in the inpatient setting longer may not be discharged to skilled-nursing care or rehabilitation care, but may receive home health and additional physician services in both the inpatient and outpatient settings that increase the costs of care. NCHA encourages CMS to take a broader look at the total cost of care across a full patient episode, rather than focusing on the distinct portions of the care captured under individual payment systems.

NCHA objects to an expansion of the post-acute care transfer policy which is not in the best interests of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. This provision must be withdrawn in its final rule.

Critical Access Hospitals

Currently, a governor may certify a hospital as a "necessary provider," which allows that hospital to become a CAH even if it fails to meet the distance requirement of being more than 35 miles (or 15 miles in mountainous areas or by secondary roads) away from a PPS hospital or another CAH. The MMA terminates a state's authority to grant necessary provider status as of January 1, 2006; however, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation.

NCHA believes that CMS is exceeding its authority and independently developing a policy that is in conflict with the law. The MMA clearly established the intent of Congress to exempt current facilities from the expiration of the necessary provider waiver. Yet, for FY 2006 and beyond, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing site or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area (HPSA) and remains in a HPSA);
- Serves the same community (75 percent of same population, 75 percent of same services, 75 percent of the same staff);
- Complies with the same conditions of participation; and

- Was "under development" as of December 8, 2003 using similar criteria as the specialty hospitals guidelines (architectural plans, financing, zoning, construction bids, etc).

We believe that the date restrictions proposed by CMS are unrealistic and unreasonable. Firstly, December 8, 2003 is simply the date the MMA was signed into law and has no connection to a CAH relocation deadline in law. The ability of governors to newly approve necessary providers expires January 1, 2006, more than 2 years later than the date arbitrarily chosen by CMS for the relocation deadline. Regardless, the law expressly allows those existing providers to maintain their status after that date with no articulated restrictions. Consequently, we insist that CMS remove the arbitrary date restrictions for relocations that have no basis in law.

CAHs are often housed in old buildings that are in desperate need of renovations, but prior to converting, these facilities could not gain access to capital due to their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, not because of excessive profits, but because of the stability of Medicare reimbursements covering allowed costs. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or other essential upgrades. Such improvements will undoubtedly result in higher quality care, better patient outcomes, and more efficient service.

Many facilities need to, or choose to, rebuild on a new site to be closer to a highway, connect to municipal water and sewer, because of seismic safety concerns, or other reasons that again, will improve patient safety and the quality of care provided. In addition, many CAHs are landlocked with little or no room for expansion, thus they have no choice but to relocate if they must rebuild. Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.

NCHA believes CMS has gone too far in trying to paint hospitals that are moving a few miles from their current location as having ceased business and reopened as a new provider. This shows a general lack of knowledge about rural areas. These CAHs are integral to their communities and often one of the biggest employers. Moving down the road will not demonstrably change the population served. We further assert that CMS automatically should consider any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.

If a CAH moves further than five miles, and CMS is concerned about whether the same population is being served, then we would recommend an approach similar to the 75 percent test described earlier. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff, and providing 75 percent of the same services are warranted.

Therefore, NCHA recommends that CMS alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show, through a needs assessment, that the change in services provided would be appropriate, then the test of 75 percent of the services should not need to be met. If a CAH has undertaken a cost comparison that shows that a new facility on another site would be

less expensive than rebuilding on the current location, then only two other measures should need to be satisfied. A combination of criteria suggested would offer CAHs some flexibility and allow for the natural development and maturation of the CAH and the community.

Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when counting the staff, how should the hospital ascertain if the staff would continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? Is the fact that you plan to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. CAHs need clear expectations and advanced warning of the standards to which they will be held.

CAHs are the sole providers of inpatient acute-care services in their communities and often outpatient and long-term care services. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. It is. thus, unlikely that they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement, there would be other hurdles such as getting licensed for additional beds in North Carolina, a certificate of need state, or hiring additional staff to expand services when there are shortages in many areas, that would need to be surmounted in an effort to build volume to survive under the PPS. For many of these CAHs, loss of their status would force them to close. Given the role of these facilities in their communities, such closures would have devastating affects on rural healthcare access.

We urge CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care of patients and meet the needs of their communities. Instead, CMS should expand and use the criteria recommended above.

Thank you for considering NCHA's comments in the FY 2006 proposed inpatient PPS rule. If you have questions regarding NCHA's comments, you may contact Amelia Bryant, NCHA Director of Financial Services at (919) 677-4225.

Sincerely,
NORTH CAROLINA HOSPITAL ASSOCIATION

Millie R. Harding

Millie R. Harding
Senior Vice President

MRH/hdv

Illinois Hospital Association

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**ATTN.: CMS-1500-P**

**Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, Federal Register, Volume 70, No. 85, Wednesday, May 4, 2005**

Dear Dr. McClellan:

On behalf of our approximately 190 member hospitals and health care systems, the Illinois Hospital Association (IHA) is taking this opportunity to formally comment on the proposed rule establishing new policies and payment rates for hospital inpatient services for fiscal year 2006. IHA commends the Centers for Medicare and Medicaid Services (CMS) for its exhaustive and thorough analyses that are presented in this rule. However, the expansion of the transfer rule, the proposed limitations placed on critical access hospital expansion projects and the potential underestimation of the market basket index, among others, cause considerable concern. Therefore, the Illinois Hospital Association presents the following comments for your consideration:

## PAYMENT PROVISIONS:

- **Market Basket Increase:** Current law (The Medicare Modernization Act of 2003-'MMA') sets the FY 2006 inpatient PPS update for hospitals at the rate of increase in the market basket, now estimated at 3.2 percent. Legislative and proposed regulatory changes, however, along with technical adjustments to ensure budget neutrality would result in a proposed average per case payment increase of only 2.5 percent. At the same time, the current estimates of the actual market basket increase for FY 2005 is 4.1 percent. IHA is concerned that CMS is dramatically underestimating the market basket for FY 2006. For seven of the last eight years, the market basket projection has been lower than the actual increase. For example, the actual increase in FY 2003 was 3.9 percent while the projected increase was 3.5 percent. In FY 2004 the actual was 3.8 percent compared to a 3.4 percent projection. CMS reports that, based on the most recent data, the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. Given a 4.1 percent cost increase for FY 2005, a projected FY 2006 increase of

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3.2 percent does not seem reasonable. **IHA requests that CMS review the methodology that was used to determine the projected FY 2005 market basket and incorporate it into the FY 2006 projection. The Association also urges CMS to make the details of the calculation available to the public.**

- **Labor-Related Portion of the Standardized Rates:** CMS proposes to reduce the labor portion of the standardized rate for FY 2006 from 71.1% to 69.7%; this change, if adopted will adversely affect hospitals whose wage index is greater than 1.0. CMS rationalizes the reduction as a result of the removal of "postage" expense from the labor category. While this adjustment does make sense, it is not clear from the rule as to whether or not CMS investigated other expense categories, particularly in the "non-labor" category that could qualify as labor costs. **Therefore, the IHA recommends that CMS incorporate no changes to the labor / non-labor portions of the standardized rates until a more thorough analysis of the specific components is completed.**

- **Proposed expansion of the transfer rule:** Medicare patients categorized in certain acute care DRGs who are discharged to a post-acute care settings, such as rehabilitation hospitals and units, long-term care hospitals, or skilled nursing facilities, or are discharged within three days to home health services are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount, up to the full inpatient PPS rate. Currently, there are 30 DRGs that are subject to this transfer rule. The criteria for determining these DRGs are:

  1. DRGs with at least 14,000 transfer cases,
  2. DRGs where at least ten percent of all cases were transferred to post acute settings before the geometric mean length of stay,
  3. DRGs with at least a seven percent decline in length of stay over the past five years,
  4. DRGs with a geometric mean length of stay of at least three days.

  In what is becoming an annual event, CMS has proposed to increase the number of DRGs subject to the transfer rule from the current 30 to 231. Specifically, CMS proposes to expand the application of the post-acute care transfer policy to any DRG that meets one of the following criteria:

  1. At least 2,000 discharges to post-acute care,
  2. At least 20 percent of its discharges are to post-acute care,
  3. At least 10 percent of its discharges to post-acute care occur before the geometric mean length of stay for the DRG,
  4. A geometric mean length of stay of at least three days and
  5. The DRG is one of a paired set of DRGs based on the presence or absence of a co-morbidity or complication; in this case, both paired DRGs are included if either one meets the first three criteria above.

**IHA believes that any expansion to the transfer rule is bad public health policy for the following reasons:**

1. **This expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system.** The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay are generally paid less than costs while cases with shorter than average stays are generally paid more than costs. Hospitals face financial challenges if a patient is discharged prior to the mean length of stay, and they face financial challenges if patients are discharged after the mean length of stay.

2. The statute clearly states that the Secretary is authorized, but not required, to expand the transfer policy.

3. **The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place.** The policy disadvantages hospitals that make sound clinical judgments about the best setting of care for patients; hospitals should not be penalized for greater than average efficiency.

4. **The post-acute transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist.** When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. If CMS is concerned about premature discharges, IHA recommends that it focus on improving the quality review process rather than further expand the transfer provision.

- **Payments for New Technologies:** In its proposed rule, CMS sets the payment amount for new technologies at 50% of the difference between the standard DRG payment and the cost of the procedure (inclusive of the new technology). **The Illinois Hospital Association strongly recommends that CMS raise this payment threshold to 80% of that difference; an increase to 80% would reflect a consistency with the current 80% marginal cost factor used in the payment calculation for outlier cases.**

- **Increased payments for low-volume hospitals:** Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per-case of low-volume hospitals. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges during the year. The rule proposes to maintain a 25 percent increase, the maximum allowable, in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS proposes to

maintain its current policy, applying no payment increase. Only 10 hospitals currently are receiving this adjustment. **The IHA is concerned that CMS is ignoring congressional intent and denying a group of hospitals – those with over 200 discharges but less than 800 discharges – access to this necessary payment increase.**

**REPORTING OF QUALITY DATA:**

To determine if a hospital qualifies for its full Medicare market basket update in FY 2006, CMS must determine if a hospital has submitted data on the 10 measures of heart attack, heart failure, and pneumonia care that were the starter set for the Hospital Quality Alliance. The proposed rule for FY 2006 states several requirements for data to be considered submitted for purposes of receiving the full market basket update. These requirements include the hospital's continuous submission of quarterly data on the 10 measures; the submission of the data for patients discharged through the 4th quarter of 2004 by May 15, 2005; and the validation of the hospital's 3rd quarter 2004 data.

To pass validation, the hospital must send copies of the relevant medical record information from five patient records chosen at random from among those on whom the hospital has submitted data. CMS has contracted with an organization that will re-abstract all of the required data from the five records. If there is at least an 80 percent agreement between the information that the contractor has abstracted and the information the hospital abstracted for all of the measures that are applicable to those patients, then the hospital will have passed validation. If not, then the contractor will compare only those data elements that are required for the 10 required measures. If there is at least an 80 percent agreement on those required elements, then the hospital will have passed validation. If the hospital has not passed validation, it can appeal the results of the contractor's work to the contractor. The state's Quality Improvement Organization will review and recommend to the contractor a disposition of the appeal. The contractor will reassess the hospital's submission in light of this additional information. Finally, if the hospital is unsuccessful in its appeal, it can ask that its 4th quarter data be used as well to determine validation. The hospital will have to submit the five randomly selected charts from its 4th quarter discharges by August 1, which is ahead of the normal schedule, and the contractor will use both the 3rd and 4th quarter charts to determine if the data validate at least 80 percent of the time.

IHA strongly supports the need for validation of the data that are submitted for the HQA. Validation is helpful in assuring that all information is being collected and processed similarly so that the publicly reported data create a reliable picture of the quality of care provided in each participating hospital. **However, the law only calls for the submission of the data for hospitals to qualify to receive the full payment update.** The Association believes that Congress recognized that taking submitted data and turning it into information that could be publicly reported is a process, and that there could be imperfections in that process. In linking payment to the submission of data, Congress suggested that hospital payments should not be held hostage to CMS or its contractors being able to correctly carry out the processing of the hospital data.

To date, there is enough evidence of flaws in the validation process to suggest that passing validation should not be a criterion for receiving the full Medicare market basket update. The validation process is sufficiently flawed that when it identifies a problem, one can only conclude that there is a difference between the information the hospital submitted and the data the contractor abstracted. No assumption can be made about which organization has correctly abstracted the data from the medical records. There have been numerous problems including logistical issues such as failure to get the request for the five files into the hands of a responsible authority at the hospital. In addition, data collection issues have arisen such as the misalignment of the data abstraction instructions hospitals were allowed to use and the instructions that the contractor had to adhere to in re-abstracting the data. Furthermore, processing issues have occurred such as the fact that hospitals have submitted appeals indicating why their data submissions were correct and the contractor's re-abstractions were incorrect, have had their quality improvement organizations verify to the contractor that the hospital has correctly submitted the data, and had their appeals turned down without explanation. **However, until the validation process is reliable, IHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update. The CMS' validation process is not currently reliable and needs improvement before it is used in determining which hospitals receive full updates.**

**WAGE INDEX CHANGES:**

- **Reclassification of Rural Status:** Although the changes to the wage index are not as extensive for FY 2006, IHA believes there is still a likelihood that revisions made between the proposed and final rules may impact a hospital's choice of whether to accept the out-migration adjustment or whether to apply for geographic reclassification. **Thus, the IHA requests that CMS implement a policy similar to last year's and allow hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the date that the Final Rule is published.**

- **Out Migration Adjustment:** For FY 2006, the second year of the three-year, out-migration adjustment, CMS is applying adjustments that are identical in amount to the adjustments given to qualifying hospitals in FY 2005. IHA does not believe that the governing statute, Section 505 of the MMA, requires that the adjustments be identical for all three years; the statute only requires that the adjustment be granted for a three-year period. It is not logical or fair to freeze the amount of the adjustment for three years. Because of changes in the wage index each year, some hospitals will be receiving out-migration adjustments even though the wage index for their geographic area is now higher than the wage index for the county to which their residents are commuting. Likewise, there may be hospitals that would be entitled to a higher out-migration adjustment if it were recalculated based on the new wage indexes for FY 2006. The three-year eligibility period for the out-migration adjustment is similar to the three-year eligibility period for geographic reclassifications, but the wage indexes for the latter change each year despite the guaranteed three-year reclassification. **IHA recommends that CMS revise its**

**policy so that the out-migration adjustment will be recalculated each year based on updated wage data and the new wage indexes.**

- **Urban Hospitals to Be Classified as Rural:** In the FY 2005 final rule, hospitals in FY 2004 that were classified as "urban", but would have become "rural" in 2005, were given a three-year transition period to review their operations and submit reclassification requests. **IHA supports the fact that CMS continues this provision in the proposed FY 2006 rules.**

- **Rural Hospitals To Be Classified as Urban:** Urban hospitals that are located in counties that are now reclassified as "rural" are given a three-year, "hold-harmless" period. CMS proposes to allow them to maintain their assignment to the MSA where they are currently located for the 3-year period from FY 2005 through FY 2007. However, CMS is silent as to the treatment of rural hospitals that will be losing their rural status. There are many rural PPS hospitals classified as rural referral centers, sole community hospitals or Medicare dependent hospitals that would rather keep their rural status and give up their special designations. Also, those rural hospitals receive additional payments under the Medicare prospective payment systems for rehabilitation, skilled nursing and home health services that would be lost if the classification were changed. For those hospitals, IHA requests the following:

  1. CMS should clarify in the final rule what options these hospitals have to elect rural status.
  2. "Grandfather" existing rural facilities in order for them to retain the increased payments for non-acute care services.

**CRITICAL ACCESS HOSPITALS: RELOCATION ISSUE:** A state's authority to grant necessary provider status, and thus waive the distance requirement under the CAH program, expires January 1, 2006. However, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS' FY 2006 proposed rule essentially bars necessary providers from ever rebuilding more than 250 yards from their current location. Appropriate and necessary relocations that result in higher quality care, better patient outcomes, and more efficient service should be allowed. **IHA urges CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care of and meet the needs of their communities.** CAHs are often housed in old buildings that are in desperate need of renovations, but prior to converting, these facilities could not gain access to capital due to their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, not because of excessive profits, but because of the stability of Medicare reimbursements covering allowed costs. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or

other essential upgrades. **Such improvements will undoubtedly result in higher quality care, better patient outcomes, and more efficient service. Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.**

IHA also encourages CMS to consider special provisions for hospitals that are merging. Under these circumstances, the two hospitals may not be able to meet the criteria. In these cases, CMS should make determinations on a case-by-case basis. If the merger meets the needs of the communities, then CMS should consider it an appropriate and allowable relocation. Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when evaluating the staff, how should the hospital ascertain if the staff would continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. CAHs need clear expectations and advanced warning of the standards to which they will be held.

CAHs are the sole providers of inpatient acute-care services in their communities and often outpatient and long-term care services. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. It is thus, unlikely that they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement there would be other hurdles, such as getting licensed for additional beds in certificate of need states or hiring additional staff to expand services when there are shortages in many areas, that would need to be surmounted in an effort to build volume to survive under the PPS. For many of these CAHs, loss of their status would force them to close. Given the role of these facilities in their communities, such closures would have devastating affects on rural healthcare access. **Therefore, IHA urges CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care of and meet the needs of their communities.**

Dr. McClellan, thank you again for the opportunity to comment. The Illinois Hospital Association welcomes the opportunity to work with your agency in the continued development and refinement of the Medicare payment system.

Sincerely,

Thomas A. Jendro

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The Honorable Mark B. McClellan, M.D., Ph.D.
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Room 445-6
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200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1500-P, Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year (FY) 2006 Rates; Proposed Rule

Dear Mr. McClellan,

On behalf of NYU Hospitals Center, I appreciate this opportunity to submit comments on the proposed rule on the Medicare Hospital Inpatient Prospective Payment Systems (IPPS) for FY 2006, as published in the May 4, 2005, *Federal Register*.

Post Acute Transfer Policy

NYU Hospitals Center is most concerned about the proposed policies of extending DRGs to 231 in the post-acute transfer policy. This regulation is not in the best interest of our patients. The financial impact on NYU Hospitals would be $3.1 million. Such a tremendous cut in payment is inappropriate and destructive to the goal of achieving high quality health care for our patients.

Patients must be placed in the most appropriate level of care, given their individual health factors and complications. We want to be sure that each patient receives the care he or she needs to reach the highest level of quality care of life and to function best in our society. The federal government and insurers should not be second guessing our well-educated and highly trained physicians on the appropriate level of care for their patients. The NYU Hospitals strongly opposes the post-acute care transfer policy in general and we are against the expansion of this policy in the proposed FY 2006 regulation.

Hospital Wage Index

The NYU Hospitals opposes the use of "core-based statistical areas" (CBSA's) in place of MSAs that result in higher payments to certain hospitals, at the expense of others. I urge you to hold harmless those hospitals that would suffer significant losses as a result of this revision.

Thank you for your consideration of these comments.

Sincerely,

Gilda V. Ecroyd

Gilda Ventresca-Ecroyd

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June 21, 2005

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Department of Health and Human Services
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Baltimore, MD 21244-1850

Reference: CMS-1500-P

Dear Administrator McClellan:

On behalf of the four hundred members of the Louisiana Rural Health Association (LRHA), I express to you our appreciation for the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems and fiscal year 2006 rates, published in the May 4, 2005 *Federal Register*.

Since its formation in 1992, LRHA has been a leader in providing educational and advocacy opportunities relating to rural health for its membership. Programming is designed to enhance the professional skills of rural health professionals and administrators and to keep them abreast of the latest legislative issues while association continuing education workshops address a wide variety of topics including quality, recruitment, health care reform and reimbursement just to name a few.

LRHA recognizes that rural areas are unique and differ from urban areas in their geography, population mix and density, economies, lifestyle, values, and social organization. Rural people and communities require programming and advocacy that responds to their unique characteristics and needs. Through discussion and exploration, LRHA works to create a clear understanding of rural health care in Louisiana, its needs and effective ways to meet these needs.

LRHA members have two very specific concerns relative to the Centers for Medicare and Medicaid Services (CMS) proposed policy change relating to designation of CAHs as Necessary Providers.

Our comments are as follows:

*CAH Replacement Facilities*

1.) We strongly oppose **all deadlines** for actions related to Critical Access Hospital replacement or relocation in the FY 2005 Inpatient Prospective Payment System (IPPS) Final Rule (69 FR 49220).

2.) The proposed rule will result in ineffective allocation of resources – both financial and staffing.

Our basis for this position is as follows:

1.) Cost projections secured by the administrator of a CAH hospital in rural Southeast Louisiana to build a new facility are $15.9 million; cost projections to renovate the same facility are $14.4 million. In a newly constructed facility, the CAH would realize efficiencies of staff that are unattainable in a facility renovated at a cost of $14.4 million. According to the CAH administrator, the newly constructed facility would be designed to allow for staffing efficiencies that could never be realized in a renovated facility. In this facility alone, the CAH Administrator projected a cost savings of $30,000 - $40,000 per month on staffing; this is staff that would no longer be required as efficiencies in staffing would be realized through department location and building design.

2.) A CAH in rural South Louisiana, which has identified and begun planning new construction, is land locked. If not allowed to construct a new facility, due to geographic limitations the CAH will lose its heliport to accommodate parking for patients and staff.

3.) A CAH in South Louisiana which downsized from 55 beds to 25 is still required to heat, cool, and clean the unused portion of the facility. There was a consideration to and a short time during which this portion was not heated, cooled, and cleaned resulting in almost immediate mold growth which negatively impacted the quality of care in the facility.

4.) Facility renovations at one CAH were projected to take between three and four years with disruption of services for rural residents. New construction for these same facilities has been projected at fourteen months with no disruption of services for rural residents.

5.) According to a CAH administrator in rural Louisiana, the average temperature inside the facility is between 78 and 80 degrees. The projected cost to impact the temperature through updating of equipment is approximately $125,000. This projected cost does not take into consideration the domino effect so many CAHs realize when repairs are required or begun. Often, what is projected to be a minor repair results in an expenditure in the thousands of dollars because, as one CAH administrator described, "the leaking pipe effected the roof that resulted in the required removal of asbestos from the ceiling that resulted in the purchase of new materials for the ceiling and laborers to perform the extended repairs."

In conclusion, I would like to address the cost and potential expansion of the CAH program as well as what seems to be some concern on the part of CMS relative to the issue by putting the CAH program expenditure in perspective.

The potential number of CAHs is less than 1500 nationwide. Since more than 1100 hospitals have already converted to CAH status, less than 400 hospitals remain eligible for CAH

designation. The total cost of the CAH program annually is approximately $3 billion; the total annual hospital budget for CMS $239 billion. Thus, the total CAH program expenditure is less than 0.01% of the total annual CMS hospital budget.

Again, I appreciate the opportunity to submit comments on the proposed rule on behalf of the members of the Louisiana Rural Health Association. If you have any questions about the comments, please do not hesitate to contact me.

Sincerely,

Donna E. Newchurch, M.A.
Executive Director